United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	◉	◉	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: July 14, 2009 (v11)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	July 2009
Overall Status:	Active, not recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	July 14, 2009
Last Update Posted:	July 15, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	◉	◉	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: June 18, 2009 (v10)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	June 2009
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	June 18, 2009
Last Update Posted:	June 19, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Artesia, California, United States, 90701

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

[Recruiting]

Sacramento, California, United States, 95819

[Recruiting]

Santa Ana, California, United States, 92705

United States, Connecticut

[Recruiting]

Hamden, Connecticut, United States, 06518

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Lauderdale, Florida, United States, 33334

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Ocala, Florida, United States, 34474

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Terminated]

Honolulu, Hawaii, United States, 96815

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21287

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Missouri

[Recruiting]

Kansas City, Missouri, United States, 64108

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

New Brunswick, New Jersey, United States, 08901

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

[Recruiting]

Raleigh, North Carolina, United States, 27607

United States, Ohio

[Recruiting]

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Terminated]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Arlington, Texas, United States, 76012

[Recruiting]

Austin, Texas, United States, 78705

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

San Antonio, Texas, United States, 78215

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

Austria

[Recruiting]

Wien, Austria, 1090

Canada, British Columbia

[Recruiting]

Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

[Recruiting]
London, Ontario, Canada, N6A 4G5

[Recruiting]
Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls | Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	◉	◉	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: June 2, 2009 (v9)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	June 2009
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	June 2, 2009
Last Update Posted:	June 4, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Artesia, California, United States, 90701

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

[Recruiting]

Sacramento, California, United States, 95819

[Recruiting]

Santa Ana, California, United States, 92705

United States, Connecticut

[Recruiting]

Hamden, Connecticut, United States, 06518

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Lauderdale, Florida, United States, 33334

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Ocala, Florida, United States, 34474

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Recruiting]

Honolulu, Hawaii, United States, 96815

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21287

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Missouri

[Recruiting]

Kansas City, Missouri, United States, 64108

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

New Brunswick, New Jersey, United States, 08901

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

[Recruiting]

Raleigh, North Carolina, United States, 27607

United States, Ohio

[Recruiting]

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Arlington, Texas, United States, 76012

[Recruiting]

Austin, Texas, United States, 78705

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

San Antonio, Texas, United States, 78215

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

Canada, British Columbia

[Recruiting]

Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

[Recruiting]

London, Ontario, Canada, N6A 4G5

[Recruiting]

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	◉	◉	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: May 27, 2009 (v8)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	May 2009
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	May 27, 2009
Last Update Posted:	May 28, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Artesia, California, United States, 90701

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

[Recruiting]

Sacramento, California, United States, 95819

[Recruiting]

Santa Ana, California, United States, 92705

United States, Connecticut

[Recruiting]

Hamden, Connecticut, United States, 06518

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Lauderdale, Florida, United States, 33334

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Ocala, Florida, United States, 34474

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Recruiting]

Honolulu, Hawaii, United States, 96815

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21287

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Missouri

[Recruiting]

Kansas City, Missouri, United States, 64108

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

New Brunswick, New Jersey, United States, 08901

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

[Recruiting]

Raleigh, North Carolina, United States, 27607

United States, Ohio

[Recruiting]

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Arlington, Texas, United States, 76012

[Recruiting]

Austin, Texas, United States, 78705

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

San Antonio, Texas, United States, 78215

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

Canada, British Columbia

[Recruiting]

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

[Recruiting]

London, Ontario, Canada, N6A 4G5

[Recruiting]

Mississuaga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	◉	◉	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: April 24, 2009 (v7)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	April 2009
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	April 24, 2009
Last Update Posted:	April 27, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Artesia, California, United States, 90701

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

[Recruiting]

Sacramento, California, United States, 95819

[Recruiting]

Santa Ana, California, United States, 92705

United States, Connecticut

[Recruiting]

Hamden, Connecticut, United States, 06518

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Lauderdale, Florida, United States, 33334

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Ocala, Florida, United States, 34474

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Recruiting]

Honolulu, Hawaii, United States, 96815

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21287

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Missouri

[Recruiting]

Kansas City, Missouri, United States, 64108

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

New Brunswick, New Jersey, United States, 08901

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

[Recruiting]

Raleigh, North Carolina, United States, 27607

United States, Ohio

[Recruiting]

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Arlington, Texas, United States, 76012

[Recruiting]

Austin, Texas, United States, 78705

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

San Antonio, Texas, United States, 78215

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	◉	◉	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: March 12, 2009 (v6)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	March 2009
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	March 12, 2009
Last Update Posted:	March 16, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Artesia, California, United States, 90701

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

[Recruiting]

Sacremento, California, United States, 95819

United States, Connecticut

[Recruiting]

Hamden, Connecticut, United States, 06518

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Ocala, Florida, United States, 34474

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Hawaii

[Recruiting]

Honolulu, Hawaii, United States, 96815

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

[Recruiting]

Raleigh, North Carolina, United States, 27607

United States, Pennsylvania

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Austin, Texas, United States, 78705

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

San Antonio, Texas, United States, 78215

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	◉	◉	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: February 13, 2009 (v5)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	February 2009
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	February 13, 2009
Last Update Posted:	February 17, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Artesia, California, United States, 90701

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

United States, Pennsylvania

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Austin, Texas, United States, 78705

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

Double-Masked Study of Safety and Efficacy of VEGF Trap-Eye in Subjects With DME (VEGF)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	◉	◉	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: February 11, 2009 (v4)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	Double-Masked Study of Safety and Efficacy of VEGF Trap-Eye in Subjects With DME (VEGF)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	February 2009
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	February 11, 2009
Last Update Posted:	February 13, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

United States, Pennsylvania

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Houston, Texas, United States, 77030

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: Investigation of Clinical Impact (DAVINCI) (VEGF)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	◉	◉	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00789477

Submitted Date: February 5, 2009 (v3)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: Investigation of Clinical Impact (DAVINCI) (VEGF)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	February 2009
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	February 5, 2009
Last Update Posted:	February 9, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

United States, South Carolina

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Houston, Texas, United States, 77030

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 2904

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

Double-Masked Study of Safety and Efficacy of VEGF Trap-Eye in Subjects With DME (VEGF)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	◉	◉	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: December 5, 2008 (v2)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	Double-Masked Study of Safety and Efficacy of VEGF Trap-Eye in Subjects With DME (VEGF)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	December 2008
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	December 5, 2008
Last Update Posted:	December 9, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Indiana**

[Active, not recruiting]
Indianapolis, Indiana, United States, 46280

United States, Massachusetts

[Active, not recruiting]
Boston, Massachusetts, United States, 02114

United States, Michigan

[Active, not recruiting]
Ann Arbor, Michigan, United States, 48104

United States, Nebraska

Eye Surgical Associates
[Recruiting]
Lincoln, Nebraska, United States, 68506

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

Double-Masked Study of Safety and Efficacy of VEGF Trap-Eye in Subjects With DME (VEGF)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	◉	◉	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00789477

Submitted Date: November 7, 2008 (v1)

Study Identification

Unique Protocol ID:	VGFT-OD-0706.01
Brief Title:	Double-Masked Study of Safety and Efficacy of VEGF Trap-Eye in Subjects With DME (VEGF)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	November 2008
Overall Status:	Not yet recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	November 7, 2008
Last Update Posted:	November 11, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye
5 Non-drug comparator	Non-drug intervention

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity

Secondary Outcome Measures:

2. Change from baseline in foveal thickness

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema

- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogeninc drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Nebraska**

Lincoln, Nebraska, United States, 68506

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye [Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)] INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification

Version	A	B	Submitted Date	Changes
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	◉	◉	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00789477

Submitted Date: August 28, 2014 (v17)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye [Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)] INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	August 2014
Overall Status:	Completed
Study Start:	December 2008
Primary Completion:	December 2009 [Actual]
Study Completion:	September 2010 [Actual]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Results First Submitted:	August 28, 2014
Results First Submitted that Met QC Criteria:	August 28, 2014

Results First Posted:	September 9, 2014 [Estimate]
Certification/Extension First Submitted:	April 19, 2011
Certification/Extension First Submitted that Met QC Criteria:	May 2, 2011
Certification/Extension First Posted:	May 5, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	August 28, 2014
Last Update Posted:	September 9, 2014 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) in subjects with diabetic macular edema (DME). Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions: Diabetic Macular Edema

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms: 5

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 221 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Intravitreal Aflibercept Injection .5Q4 Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) .5 mg every 4 weeks	Drug: Intravitreal Aflibercept Injection Other Names: • IAI; EYLEA®; BAY86-5321; VEGF Trap-Eye
Experimental: Intravitreal Aflibercept Injection 2Q4 Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2 mg every 4 weeks	Drug: Intravitreal Aflibercept Injection Other Names: • IAI; EYLEA®; BAY86-5321; VEGF Trap-Eye
Experimental: Intravitreal Aflibercept Injection 2Q8 Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2mg every 4 weeks for 3 visits followed by every 8 weeks	Drug: Intravitreal Aflibercept Injection Other Names: • IAI; EYLEA®; BAY86-5321; VEGF Trap-Eye

Arms	Assigned Interventions
Experimental: Intravitreal Aflibercept Injection 2PRN Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2mg every 4 weeks for 3 visits followed by PRN (as-needed) dosing according to the re-treatment criteria	Drug: Intravitreal Aflibercept Injection Other Names: • IAI; EYLEA®; BAY86-5321; VEGF Trap-Eye
Active Comparator: Laser Photocoagulation Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re- treatment was permitted no more than once every 16 weeks.	Procedure: Laser Photocoagulation laser every 16 weeks as needed Other Names: • macular laser therapy

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening

- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Clinical Trial Management
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	A total of 221 participants were randomized at 39 sites in the US, Canada, and Austria. After the 1 year treatment period, participants were to be followed for safety in a 6 mo. follow-up phase. The last visit for this study occurred in September, 2010.
Pre-assignment Details	The study population consisted of men and women aged 18 or older with clinically significant diabetic macular edema (DME) with central involvement, and a best corrected visual acuity (BCVA) of 20/40 to 20/320 (letter score of 73 to 24) in the study eye.

Reporting Groups

	Description
Laser Photocoagulation	Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re- treatment was permitted no more than once every 16 weeks.
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321).5Q4	Intravitreal Aflibercept Injection (IAI) 0.5 mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q4	Intravitreal Aflibercept Injection (IAI) 2 mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q8	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by every 8 weeks through week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)2PRN	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by PRN (as-needed) dosing according to the re-treatment criteria to week 52

Overall Study

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Started	44 [1]	44 [1]	44 [1]	44 [1]	45 [1]
Participants Received Treatment	44 [2]	44 [3]	44 [3]	42 [3]	45 [3]
Completed	33	38	33	34	38
Not Completed	11	6	11	10	7
Withdrawal by Subject	2	1	3	2	3
Protocol Violation	1	0	0	1	0
Adverse Event	3	3	1	0	0
Death	1	1	2	2	0
Lost to Follow-up	0	1	4	2	4
Lack of Efficacy	2	0	0	0	0
Other	2	0	1	3	0

[1] randomized

[2] safety analysis set (SAF)

[3] SAF

Baseline Characteristics

Baseline Analysis Population Description

Full analysis set (FAS): included all randomized patients who received any study drug, had baseline assessments, and had at least one (1) post-baseline assessment.

Reporting Groups

	Description
Laser Photocoagulation	Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re- treatment was permitted no more than once every 16 weeks.
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321).5Q4	Intravitreal Aflibercept Injection (IAI) 0.5mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q4	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q8	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by every 8 weeks through week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)2PRN	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by PRN dosing according to the re-treatment criteria to week 52

Baseline Measures

		Laser Photocoagula	Intravitreal Aflibercept Injection (IAI;EYLEA®; 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®; 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®; 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®; 5321)2PRN	Total
Overall Number of Participants		44	44	44	42	45	219
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	44 Participants	44 Participants	44 Participants	42 Participants	45 Participants	219 Participants
		64.0 (8.12)	62.3 (10.70)	62.1 (10.50)	62.5 (11.49)	60.7 (8.66)	62.3 (9.92)
Sex: Female, Male Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	44 Participants	44 Participants	44 Participants	42 Participants	45 Participants	219 Participants
	Female	17 38.64%	20 45.45%	17 38.64%	20 47.62%	16 35.56%	90 41.1%
	Male	27 61.36%	24 54.55%	27 61.36%	22 52.38%	29 64.44%	129 58.9%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change in BCVA From Baseline to Week 24 - Last Observation Carried Forward (LOCF)
Measure Description	Visual function of the study eye was assessed using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol at 4 meters. Measurements were taken at every study visit. Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).
Time Frame	At week 24

Analysis Population Description

The FAS was used for the primary efficacy analysis. It included patients as randomized.

Reporting Groups

	Description
Laser Photocoagulation	Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re- treatment was permitted no more than once every 16 weeks.
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321).5Q4	Intravitreal Aflibercept Injection (IAI) 0.5mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q4	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by every 8 weeks through week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q8	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by every 8 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)2PRN	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by PRN dosing according to the re-treatment criteria to week 52

Measured Values

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321)2PRN
Overall Number of Participants Analyzed	44	44	44	42	45
Change in BCVA From Baseline to Week 24 - Last Observation Carried Forward (LOCF) Measure Type: Mean (Standard Deviation) Unit of Measure: letters correctly read	2.5 (16.14)	8.6 (14.64)	11.4 (8.67)	8.5 (7.50)	10.3 (7.52)

2. Secondary Outcome Measure:

Measure Title	Change in BCVA From Baseline to Week 52 - LOCF
Measure Description	Visual function of the study eye was assessed using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol at 4 meters. Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).
Time Frame	At week 52

Analysis Population Description

FAS

Reporting Groups

	Description
Laser Photocoagulation	Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re- treatment was permitted no more than once every 16 weeks.
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321).5Q4	Intravitreal Aflibercept Injection (IAI) 0.5 mg every 4 weeks to week 52

Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q4	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q8	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by every 8 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)2PRN	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by PRN dosing according to the re-treatment criteria to week 52

Measured Values

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BA 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BA 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BA 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BA 5321)2PRN
Overall Number of Participants Analyzed	44	44	44	42	45
Change in BCVA From Baseline to Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: letters correctly read	-1.3 (20.72)	11.0 (15.40)	13.1 (10.54)	9.7 (8.93)	12.0 (11.09)

3. Secondary Outcome Measure:

Measure Title	Participants With Gains in ETDRS Letter Score of at Least 15 Letters - LOCF
Measure Description	Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).
Time Frame	At week 24 and week 52

Analysis Population Description

FAS

Reporting Groups

	Description
Laser Photocoagulation	Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re- treatment was permitted no more than once every 16 weeks.
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321).5Q4	Intravitreal Aflibercept Injection (IAI) 0.5 mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q4	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q8	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by every 8 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)2PRN	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by PRN dosing according to the re-treatment criteria to week 52

Measured Values

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321)2PRN
Overall Number of Participants Analyzed	44	44	44	42	45
Participants With Gains in ETDRS Letter Score of at Least 15 Letters - LOCF Measure Type: Number Unit of Measure: participants					
At week 24	9	15	14	7	12
At week 52	5	18	20	10	19

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Central Retinal Thickness (CRT) as Assessed by Optical Coherence Tomography (OCT) - LOCF
Measure Description	Retinal thickness was evaluated using OCT at every visit except week 1. Missing values were imputed with post-baseline values during on-treatment period by using last observation carried forward (LOCF).
Time Frame	At week 24 and week 52

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Laser Photocoagulation	Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re- treatment was permitted no more than once every 16 weeks.
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321).5Q4	Intravitreal Aflibercept Injection (IAI) 0.5 mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q4	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q8	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by every 8 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)2PRN	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by PRN dosing according to the re-treatment criteria to week 52

Measured Values

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY 5321)2PRN
Overall Number of Participants Analyzed	43	44	44	42	45
Change From Baseline in Central Retinal Thickness (CRT) as Assessed by Optical Coherence Tomography (OCT) - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: microns					
At week 24	-67.9 (135.17)	-144.6 (110.65)	-194.5 (143.04)	-127.3 (141.78)	-153.3 (132.17)
At week 52	-58.4 (177.60)	-165.4 (135.72)	-227.4 (148.96)	-187.8 (135.01)	-180.3 (124.43)

5. Secondary Outcome Measure:

Measure Title	Number of Focal Laser Treatments
Measure Description	
Time Frame	Week 1 to week 48

Analysis Population Description

For the first 24 weeks, the Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) groups did not receive laser treatment. From week 24 onward, participants in the Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) groups were allowed to receive laser rescue treatment.

Reporting Groups

	Description

Laser Photocoagulation	Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re- treatment was permitted no more than once every 16 weeks.
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321).5Q4	Intravitreal Aflibercept Injection (IAI) 0.5 mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q4	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q8	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by every 8 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)2PRN	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by PRN dosing according to the re-treatment criteria to week 52

Measured Values

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BA 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BA 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BA 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BA 5321)2PRN
Overall Number of Participants Analyzed	44	44	44	42	45
Number of Focal Laser Treatments Measure Type: Mean (Standard Deviation) Unit of Measure: Treatments	2.5 (0.87)	0.8 (0.93)	0.5 (0.66)	0.8 (0.86)	0.7 (0.77)

Reported Adverse Events

Time Frame	Day 1 to week 52
Adverse Event Reporting Description	Safety analysis set (SAF): included all patients who received any study drug. The SAF was used for all safety and tolerability assessments. Safety analysis included patients as treated.

Reporting Groups

	Description
Laser Photocoagulation	Focal laser at week 1, and one week after visits at which the participant met laser re-treatment criteria to the end of the study (week 52) starting at week 16; laser re- treatment was permitted no more than once every 16 weeks.
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321).5Q4	Intravitreal Aflibercept Injection (IAI) 0.5 mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q4	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks to week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321) 2Q8	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by every 8 weeks through week 52
Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY86-5321)2PRN	Intravitreal Aflibercept Injection (IAI) 2mg every 4 weeks for 3 visits followed by PRN dosing according to the re-treatment criteria to week 52

All-Cause Mortality

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/	/

Serious Adverse Events

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	10/44 (22.73%)	14/44 (31.82%)	13/44 (29.55%)	12/42 (28.57%)	6/45 (13.33%)
Blood and lymphatic system disorders					
Anaemia [A]	0/44 (0%)	1/44 (2.27%)	2/44 (4.55%)	0/42 (0%)	0/45 (0%)
Coagulopathy [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Haemorrhagic anaemia [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Cardiac disorders					
Acute coronary syndrome [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Acute myocardial infarction [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Angina pectoris [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Angina unstable [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Arteriosclerosis coronary artery [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Atrial fibrillation [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Cardiac failure acute [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Cardiac failure congestive [A]	0/44 (0%)	0/44 (0%)	3/44 (6.82%)	1/42 (2.38%)	2/45 (4.44%)
Coronary artery disease [A]	0/44 (0%)	1/44 (2.27%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Coronary artery occlusion [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Myocardial infarction [A]	0/44 (0%)	2/44 (4.55%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Sick sinus syndrome [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Silent myocardial infarction [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Wolff-Parkinson-White syndrome [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Eye disorders					
Angle closure glaucoma [A] [1]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Corneal abrasion [A] [1]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Cystoid macular oedema [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Diabetic retinal oedema [A] [1]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Diabetic retinopathy [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Maculopathy [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Retinal tear [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Uveitis [A] [1]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Visual acuity reduced [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Visual acuity reduced [A] [1]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Vitreous adhesions [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Vitreous haemorrhage [A] [1]	3/44 (6.82%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Vitreous haemorrhage [A]	1/44 (2.27%)	1/44 (2.27%)	1/44 (2.27%)	2/42 (4.76%)	0/45 (0%)
Gastrointestinal disorders					
Diverticulum [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Gastric ulcer [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Gastrointestinal haemorrhage [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Lower gastrointestinal haemorrhage [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Nausea [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Upper gastrointestinal haemorrhage [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Varices oesophageal [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Vomiting [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
General disorders					
Chest pain [A]	0/44 (0%)	0/44 (0%)	2/44 (4.55%)	0/42 (0%)	3/45 (6.67%)
Device occlusion [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Multi-organ failure [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Non-cardiac chest pain [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Pyrexia [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	1/42 (2.38%)	0/45 (0%)
Sudden death [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Infections and infestations					
Abscess [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Abscess limb [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Appendicitis [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Bronchitis [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Cellulitis [A]	0/44 (0%)	3/44 (6.82%)	2/44 (4.55%)	0/42 (0%)	1/45 (2.22%)
Clostridium difficile colitis [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Cystitis [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Diverticulitis [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Endophthalmitis [A] [1]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	1/45 (2.22%)
Gangrene [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Gastroenteritis [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Localised infection [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Osteomyelitis [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Parotitis [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Pneumonia [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	1/42 (2.38%)	0/45 (0%)
Sepsis [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Staphylococcal infection [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Staphylococcal sepsis [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Subcutaneous abscess [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Injury, poisoning and procedural complications					
Joint capsule rupture [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Postoperative ileus [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Thermal burn [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Traumatic brain injury [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Investigations					
Blood pressure increased [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Liver function test abnormal [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Metabolism and nutrition disorders					
Dehydration [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	2/42 (4.76%)	0/45 (0%)
Diabetic ketoacidosis [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	1/42 (2.38%)	0/45 (0%)
Fluid overload [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Hyperglycaemia [A]	0/44 (0%)	0/44 (0%)	2/44 (4.55%)	0/42 (0%)	0/45 (0%)
Hyperkalaemia [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Hypoglycaemia [A]	1/44 (2.27%)	1/44 (2.27%)	1/44 (2.27%)	1/42 (2.38%)	0/45 (0%)
Musculoskeletal and connective tissue disorders					
Lumbar spinal stenosis [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Colon cancer stage III [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Non-small cell lung cancer [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Renal cell carcinoma stage IV [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Squamous cell carcinoma of skin [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Transitional cell carcinoma [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Nervous system disorders					
Cerebral infarction [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Cerebrovascular accident [A]	1/44 (2.27%)	1/44 (2.27%)	2/44 (4.55%)	0/42 (0%)	0/45 (0%)
Convulsion [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Headache [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Hemiparesis [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Hepatic encephalopathy [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Sciatica [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Syncope [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	1/45 (2.22%)
Psychiatric disorders					
Mental status changes [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Renal and urinary disorders					
Nephropathy [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Renal failure [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Renal failure acute [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Stress urinary incontinence [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Reproductive system and breast disorders					
Benign prostatic hyperplasia [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Respiratory, thoracic and mediastinal disorders					

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Acute respiratory failure [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Dyspnoea [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Pleural effusion [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Pulmonary embolism [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Pulmonary oedema [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Respiratory failure [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Skin and subcutaneous tissue disorders					
Skin ulcer [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Vascular disorders					
Aortic stenosis [A]	0/44 (0%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Deep vein thrombosis [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Hypertension [A]	0/44 (0%)	0/44 (0%)	2/44 (4.55%)	1/42 (2.38%)	0/45 (0%)
Hypertensive crisis [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Hypertensive emergency [A]	1/44 (2.27%)	0/44 (0%)	1/44 (2.27%)	0/42 (0%)	0/45 (0%)
Hypotension [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Peripheral arterial occlusive disease [A]	1/44 (2.27%)	0/44 (0%)	0/44 (0%)	0/42 (0%)	0/45 (0%)

A Term from vocabulary, MedDRA 13.1

[1] Study eye

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	20/44 (45.45%)	22/44 (50%)	22/44 (50%)	26/42 (61.9%)	24/45 (53.33%)
Blood and lymphatic system disorders					
Anaemia [A]	2/44 (4.55%)	1/44 (2.27%)	3/44 (6.82%)	4/42 (9.52%)	5/45 (11.11%)
Eye disorders					
Blepharitis [A]	0/44 (0%)	0/44 (0%)	4/44 (9.09%)	0/42 (0%)	1/45 (2.22%)
Blepharitis [A] [1]	0/44 (0%)	0/44 (0%)	4/44 (9.09%)	0/42 (0%)	1/45 (2.22%)
Cataract [A]	1/44 (2.27%)	2/44 (4.55%)	1/44 (2.27%)	0/42 (0%)	5/45 (11.11%)
Cataract [A] [1]	2/44 (4.55%)	2/44 (4.55%)	3/44 (6.82%)	2/42 (4.76%)	5/45 (11.11%)
Conjunctival haemorrhage [A]	8/44 (18.18%)	12/44 (27.27%)	7/44 (15.91%)	15/42 (35.71%)	13/45 (28.89%)
Diabetic retinal oedema [A]	0/44 (0%)	4/44 (9.09%)	3/44 (6.82%)	0/42 (0%)	4/45 (8.89%)
Diabetic retinal oedema [A] [1]	0/44 (0%)	1/44 (2.27%)	3/44 (6.82%)	1/42 (2.38%)	3/45 (6.67%)
Eye pain [A]	3/44 (6.82%)	2/44 (4.55%)	0/44 (0%)	1/42 (2.38%)	0/45 (0%)
Eye pain [A] [1]	2/44 (4.55%)	6/44 (13.64%)	5/44 (11.36%)	6/42 (14.29%)	7/45 (15.56%)
Foreign body sensation in eye [A] [1]	0/44 (0%)	1/44 (2.27%)	1/44 (2.27%)	1/42 (2.38%)	3/45 (6.67%)
Macular oedema [A]	3/44 (6.82%)	1/44 (2.27%)	0/44 (0%)	0/42 (0%)	0/45 (0%)
Maculopathy [A] [1]	2/44 (4.55%)	2/44 (4.55%)	1/44 (2.27%)	4/42 (9.52%)	3/45 (6.67%)

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Ocular hyperaemia [A] [1]	2/44 (4.55%)	5/44 (11.36%)	2/44 (4.55%)	3/42 (7.14%)	3/45 (6.67%)
Posterior capsule opacification [A]	3/44 (6.82%)	1/44 (2.27%)	1/44 (2.27%)	1/42 (2.38%)	0/45 (0%)
Punctate keratitis [A] [1]	1/44 (2.27%)	1/44 (2.27%)	0/44 (0%)	3/42 (7.14%)	0/45 (0%)
Retinal aneurysm [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	3/42 (7.14%)	1/45 (2.22%)
Retinal aneurysm [A] [1]	1/44 (2.27%)	3/44 (6.82%)	0/44 (0%)	2/42 (4.76%)	2/45 (4.44%)
Retinal exudates [A] [1]	1/44 (2.27%)	4/44 (9.09%)	1/44 (2.27%)	2/42 (4.76%)	3/45 (6.67%)
Retinal haemorrhage [A]	3/44 (6.82%)	1/44 (2.27%)	1/44 (2.27%)	3/42 (7.14%)	5/45 (11.11%)
Retinal haemorrhage [A] [1]	2/44 (4.55%)	0/44 (0%)	3/44 (6.82%)	1/42 (2.38%)	4/45 (8.89%)
Retinal neovascularisation [A]	1/44 (2.27%)	0/44 (0%)	2/44 (4.55%)	1/42 (2.38%)	3/45 (6.67%)
Vision blurred [A] [1]	1/44 (2.27%)	4/44 (9.09%)	0/44 (0%)	0/42 (0%)	2/45 (4.44%)
Vitreous detachment [A]	3/44 (6.82%)	2/44 (4.55%)	1/44 (2.27%)	4/42 (9.52%)	0/45 (0%)
Vitreous detachment [A] [1]	5/44 (11.36%)	3/44 (6.82%)	3/44 (6.82%)	3/42 (7.14%)	0/45 (0%)
Vitreous floaters [A]	1/44 (2.27%)	0/44 (0%)	3/44 (6.82%)	2/42 (4.76%)	0/45 (0%)
Vitreous floaters [A] [1]	2/44 (4.55%)	5/44 (11.36%)	3/44 (6.82%)	2/42 (4.76%)	2/45 (4.44%)
Vitreous haemorrhage [A]	5/44 (11.36%)	3/44 (6.82%)	5/44 (11.36%)	4/42 (9.52%)	3/45 (6.67%)
Vitreous haemorrhage [A] [1]	5/44 (11.36%)	0/44 (0%)	2/44 (4.55%)	1/42 (2.38%)	1/45 (2.22%)
Gastrointestinal disorders					
Nausea [A]	1/44 (2.27%)	2/44 (4.55%)	3/44 (6.82%)	4/42 (9.52%)	4/45 (8.89%)
General disorders					

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Oedema peripheral [A]	3/44 (6.82%)	1/44 (2.27%)	1/44 (2.27%)	2/42 (4.76%)	2/45 (4.44%)
Infections and infestations					
Bronchitis [A]	1/44 (2.27%)	3/44 (6.82%)	2/44 (4.55%)	0/42 (0%)	2/45 (4.44%)
Nasopharyngitis [A]	4/44 (9.09%)	4/44 (9.09%)	3/44 (6.82%)	1/42 (2.38%)	3/45 (6.67%)
Injury, poisoning and procedural complications					
Corneal abrasion [A] [1]	0/44 (0%)	0/44 (0%)	2/44 (4.55%)	2/42 (4.76%)	3/45 (6.67%)
Investigations					
Blood glucose increased [A]	1/44 (2.27%)	4/44 (9.09%)	3/44 (6.82%)	6/42 (14.29%)	6/45 (13.33%)
Blood potassium increased [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	3/42 (7.14%)	3/45 (6.67%)
Blood pressure increased [A]	1/44 (2.27%)	1/44 (2.27%)	4/44 (9.09%)	1/42 (2.38%)	1/45 (2.22%)
Blood urine present [A]	0/44 (0%)	1/44 (2.27%)	0/44 (0%)	1/42 (2.38%)	3/45 (6.67%)
Glucose urine present [A]	1/44 (2.27%)	1/44 (2.27%)	0/44 (0%)	3/42 (7.14%)	4/45 (8.89%)
Glycosylated haemoglobin increased [A]	2/44 (4.55%)	6/44 (13.64%)	5/44 (11.36%)	5/42 (11.9%)	2/45 (4.44%)
Haematocrit decreased [A]	2/44 (4.55%)	2/44 (4.55%)	4/44 (9.09%)	0/42 (0%)	0/45 (0%)
Haemoglobin decreased [A]	2/44 (4.55%)	2/44 (4.55%)	3/44 (6.82%)	0/42 (0%)	0/45 (0%)
Intraocular pressure increased [A] [1]	1/44 (2.27%)	6/44 (13.64%)	6/44 (13.64%)	5/42 (11.9%)	2/45 (4.44%)
Protein urine present [A]	2/44 (4.55%)	1/44 (2.27%)	1/44 (2.27%)	4/42 (9.52%)	3/45 (6.67%)
Red blood cell count decreased [A]	0/44 (0%)	1/44 (2.27%)	3/44 (6.82%)	0/42 (0%)	1/45 (2.22%)

	Laser Photocoagulation	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321).5Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q4	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321) 2Q8	Intravitreal Aflibercept Injection (IAI;EYLEA®;BAY8 5321)2PRN
Metabolism and nutrition disorders					
Hypercholesterolaemia [A]	1/44 (2.27%)	1/44 (2.27%)	3/44 (6.82%)	3/42 (7.14%)	1/45 (2.22%)
Nervous system disorders					
Headache [A]	2/44 (4.55%)	0/44 (0%)	2/44 (4.55%)	3/42 (7.14%)	2/45 (4.44%)
Respiratory, thoracic and mediastinal disorders					
Asthma [A]	0/44 (0%)	0/44 (0%)	0/44 (0%)	3/42 (7.14%)	1/45 (2.22%)
Oropharyngeal pain [A]	3/44 (6.82%)	1/44 (2.27%)	1/44 (2.27%)	1/42 (2.38%)	0/45 (0%)
Vascular disorders					
Hypertension [A]	5/44 (11.36%)	5/44 (11.36%)	5/44 (11.36%)	6/42 (14.29%)	5/45 (11.11%)

A Term from vocabulary, MedDRA 13.1

[1] Study eye

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Clinical Trial Management
Organization: Regeneron
Phone: 9148475385
Email: clinicaltrials@regeneron.com

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	◉	◉	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: August 13, 2014 (v16)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	May 2011
Overall Status:	Completed
Study Start:	December 2008
Primary Completion:	December 2009 [Actual]
Study Completion:	September 2010 [Actual]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Certification/Extension First Submitted:	April 19, 2011
Certification/Extension First Submitted that Met QC Criteria:	May 2, 2011

Certification/Extension First Posted:	May 5, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	August 13, 2014
Last Update Posted:	August 15, 2014 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms: 5

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 219 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: macular laser therapy laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness

Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director

Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	◉	◉	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: September 27, 2013 (v15)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	May 2011
Overall Status:	Completed
Study Start:	December 2008
Primary Completion:	December 2009 [Actual]
Study Completion:	September 2010 [Actual]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Certification/Extension First Submitted:	April 19, 2011
Certification/Extension First Submitted that Met QC Criteria:	May 2, 2011

Certification/Extension First Posted:	May 5, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	September 27, 2013
Last Update Posted:	October 28, 2013 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms: 5

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 219 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: macular laser therapy laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness

Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director

Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	◉	◉	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: May 9, 2011 (v10)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	May 2011
Overall Status:	Active, not recruiting
Study Start:	July 2009
Primary Completion:	October 2010 [Actual]
Study Completion:	April 2012 [Anticipated]

First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]

Certification/Extension First Submitted:	May 9, 2011
Certification/Extension First Submitted that Met QC Criteria:	May 9, 2011
Certification/Extension First Posted:	May 16, 2011 [Estimate]

Last Update Submitted that Met QC Criteria:	May 9, 2011
Last Update Posted:	May 16, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.
Detailed Description:	

Conditions

Conditions:	Macular Edema Secondary to Central Retinal Vein Occlusion
Keywords:	Macular edema Retinal vein occlusion CRVO VEGF Trap-Eye best-corrected visual acuity Regeneron COPERNICUS

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 189 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Arcadia, California, United States, 91007

Beverly Hills, California, United States, 90211

La Jolla, California, United States, 92037

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Sacramento, California, United States, 95841

Torrance, California, United States, 90503

United States, Connecticut

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33907

Fort Myers, Florida, United States, 33912

Miami, Florida, United States, 33143

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Chicago, Illinois, United States, 60612

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Maryland

Baltimore, Maryland, United States, 21209

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 48104

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, Nevada

Las Vegas, Nevada, United States, 89135

United States, New Jersey

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08755

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cleveland, Ohio, United States, 44195

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Ft Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4V2

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M4N 3M5

Colombia, Antioquia

Medellin, Antioquia, Colombia

Colombia

Bogota, Colombia

India, A.p.

Hyderabad, A.p., India, 500034

India, Karnataka

Bangalore, Karnataka, India, 560010

India, West Bengal

Kolkata, West Bengal, India, 700073

Israel

Kfar-Saba, Israel, 44281

Petah Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	◉	◉	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: May 5, 2011 (v9)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	May 2011
Overall Status:	Active, not recruiting
Study Start:	July 2009
Primary Completion:	October 2010 [Actual]
Study Completion:	April 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	May 5, 2011
Last Update Posted:	May 6, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 189 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Arcadia, California, United States, 91007

Beverly Hills, California, United States, 90211

La Jolla, California, United States, 92037

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Sacramento, California, United States, 95841

Torrance, California, United States, 90503

United States, Connecticut

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33907

Fort Myers, Florida, United States, 33912

Miami, Florida, United States, 33143

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Chicago, Illinois, United States, 60612

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Maryland

Baltimore, Maryland, United States, 21209

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 48104

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, Nevada

Las Vegas, Nevada, United States, 89135

United States, New Jersey

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08755

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cleveland, Ohio, United States, 44195

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Ft Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4V2

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M4N 3M5

Colombia, Antioquia

Medellin, Antioquia, Colombia

Colombia

Bogota, Colombia

India, A.p.

Hyderabad, A.p., India, 500034

India, Karnataka

Bangalore, Karnataka, India, 560010

India, West Bengal

Kolkata, West Bengal, India, 700073

Israel

Kfar-Saba, Israel, 44281

Petah Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	◉	◉	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: February 11, 2011 (v8)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	February 2011
Overall Status:	Active, not recruiting
Study Start:	July 2009
Primary Completion:	April 2012 [Anticipated]
Study Completion:	April 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	February 11, 2011
Last Update Posted:	February 14, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 189 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Arcadia, California, United States, 91007

Beverly Hills, California, United States, 90211

La Jolla, California, United States, 92037

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Sacramento, California, United States, 95841

Torrance, California, United States, 90503

United States, Connecticut

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33907

Fort Myers, Florida, United States, 33912

Miami, Florida, United States, 33143

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Chicago, Illinois, United States, 60612

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Maryland

Baltimore, Maryland, United States, 21209

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 48104

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, Nevada

Las Vegas, Nevada, United States, 89135

United States, New Jersey

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08755

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cleveland, Ohio, United States, 44195

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Ft Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4V2

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M4N 3M5

Colombia, Antioquia

Medellin, Antioquia, Colombia

Colombia

Bogota, Colombia

India, A.p.

Hyderabad, A.p., India, 500034

India, Karnataka

Bangalore, Karnataka, India, 560010

India, West Bengal

Kolkata, West Bengal, India, 700073

Israel

Kfar-Saba, Israel, 44281

Petah Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	◉	◉	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: November 18, 2010 (v7)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	November 2010
Overall Status:	Active, not recruiting
Study Start:	July 2009
Primary Completion:	January 2011 [Anticipated]
Study Completion:	August 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	November 18, 2010
Last Update Posted:	November 19, 2010 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Arcadia, California, United States, 91007

Beverly Hills, California, United States, 90211

La Jolla, California, United States, 92037

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Sacramento, California, United States, 95841

Torrance, California, United States, 90503

United States, Connecticut

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33907

Fort Myers, Florida, United States, 33912

Miami, Florida, United States, 33143

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Chicago, Illinois, United States, 60612

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Maryland

Baltimore, Maryland, United States, 21209

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 48104

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, Nevada

Las Vegas, Nevada, United States, 89135

United States, New Jersey

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08755

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cleveland, Ohio, United States, 44195

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Ft Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4V2

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M4N 3M5

Colombia, Antioquia

Medellin, Antioquia, Colombia

Colombia

Bogota, Colombia

India, A.p.

Hyderabad, A.p., India, 500034

India, Karnataka

Bangalore, Karnataka, India, 560010

India, West Bengal

Kolkata, West Bengal, India, 700073

Israel

Kfar-Saba, Israel, 44281

Petah Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	◉	◉	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: July 2, 2010 (v6)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	April 2010
Overall Status:	Active, not recruiting
Study Start:	July 2009
Primary Completion:	January 2011 [Anticipated]
Study Completion:	August 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	July 2, 2010
Last Update Posted:	July 5, 2010 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Arcadia, California, United States, 91007

Beverly Hills, California, United States, 90211

La Jolla, California, United States, 92037

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Sacramento, California, United States, 95841

Torrance, California, United States, 90503

United States, Connecticut

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33907

Fort Myers, Florida, United States, 33912

Miami, Florida, United States, 33143

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Chicago, Illinois, United States, 60612

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Maryland

Baltimore, Maryland, United States, 21209

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 48104

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, Nevada

Las Vegas, Nevada, United States, 89135

United States, New Jersey

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08755

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cleveland, Ohio, United States, 44195

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Ft Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4V2

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M4N 3M5

Colombia, Antioquia

Medellin, Antioquia, Colombia

Colombia

Bogota, Colombia

India, A.p.

Hyderabad, A.p., India, 500034

India, Karnataka

Bangalore, Karnataka, India, 560010

India, West Bengal

Kolkata, West Bengal, India, 700073

Israel

Kfar-Saba, Israel, 44281

Petah Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	◉	◉	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: February 18, 2010 (v5)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	February 2010
Overall Status:	Recruiting
Study Start:	July 2009
Primary Completion:	January 2011 [Anticipated]
Study Completion:	August 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	February 18, 2010
Last Update Posted:	February 22, 2010 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Central Contact: Irma Alvarez
Telephone: 626-333-3213
Email: irma.alvarez@parexel.com

Central Contact Backup: Heather Evans, BA
Telephone: 914-345-7562
Email: heather.evans@regeneron.com

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

[Recruiting]
Phoenix, Arizona, United States, 85014

[Recruiting]
Phoenix, Arizona, United States, 85020

[Recruiting]
Tucson, Arizona, United States, 85704

United States, California

[Recruiting]

Arcadia, California, United States, 91007

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

La Jolla, California, United States, 92037

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Oakland, California, United States, 94609

[Not yet recruiting]

Oxnard, California, United States, 93030

[Not yet recruiting]

Sacramento, California, United States, 95817

[Recruiting]

Sacramento, California, United States, 95841

[Not yet recruiting]

Torrance, California, United States, 90503

United States, Connecticut

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Terminated]

Altamonte Springs, Florida, United States, 32701

[Recruiting]

Fort Lauderdale, Florida, United States, 33334

[Recruiting]

Fort Myers, Florida, United States, 33907

[Terminated]

Fort Myers, Florida, United States, 33912

[Not yet recruiting]
Jacksonville, Florida, United States, 32224

[Recruiting]
Miami, Florida, United States, 33143

[Recruiting]
Palm Beach Gardens, Florida, United States, 33410

[Recruiting]
Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]
Augusta, Georgia, United States, 30909

United States, Illinois

[Not yet recruiting]
Chicago, Illinois, United States, 60612

United States, Indiana

[Withdrawn]
Indianapolis, Indiana, United States, 46290

United States, Kansas

[Recruiting]
Wichita, Kansas, United States, 67214

United States, Maryland

[Recruiting]
Baltimore, Maryland, United States, 21209

[Recruiting]
Hagerstown, Maryland, United States, 21740

[Recruiting]

Towson, Maryland, United States, 21204

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Grand Rapids, Michigan, United States, 49525

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, Nevada

[Recruiting]

Las Vegas, Nevada, United States, 89135

United States, New Jersey

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08755

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Withdrawn]

Raleigh, North Carolina, United States, 27607

[Recruiting]

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

[Not yet recruiting]
Cleveland, Ohio, United States, 44195

United States, Oklahoma

[Recruiting]
Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

[Recruiting]
Portland, Oregon, United States, 97210

[Recruiting]
Salem, Oregon, United States, 97302

United States, Pennsylvania

[Recruiting]
Kingston, Pennsylvania, United States, 18704

[Not yet recruiting]
Philadelphia, Pennsylvania, United States, 19107

[Terminated]
Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Recruiting]
West Columbia, South Carolina, United States, 29169

United States, South Dakota

[Recruiting]
Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]
Abilene, Texas, United States, 79606

[Not yet recruiting]
Austin, Texas, United States, 78705

[Recruiting]
Ft Worth, Texas, United States, 76102

[Recruiting]
Houston, Texas, United States, 77030

[Recruiting]
San Antonio, Texas, United States, 78240

Canada, British Columbia

[Recruiting]
Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]
Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

[Recruiting]
Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

[Recruiting]
London, Ontario, Canada, N6A 4V2

[Recruiting]
Mississauga, Ontario, Canada, L4W 1W9

[Not yet recruiting]
Ottawa, Ontario, Canada, K1S 0P1

[Not yet recruiting]

Toronto, Ontario, Canada, M4N 3M5

Colombia, Antioquia

[Not yet recruiting]

Medellin, Antioquia, Colombia

Colombia, Valle del Cauca

[Not yet recruiting]

Cali, Valle del Cauca, Colombia

Colombia

[Not yet recruiting]

Bogota, Colombia

India, A.p.

[Not yet recruiting]

Hyderabad, A.p., India, 500034

India, Delhi

[Not yet recruiting]

New Delhi, Delhi, India, 110029

India, Karnataka

[Not yet recruiting]

Bangalore, Karnataka, India, 560010

India, Kerala

[Not yet recruiting]

Ernakulam, Kerala, India, 683572

India, Maharashtra

[Not yet recruiting]

Mumbai, Maharashtra, India, 400050

[Not yet recruiting]

Mumbai, Maharashtra, India, 400058

India, Orissa

[Not yet recruiting]
Bhubaneswar, Orissa, India, 751024

India, Pondy

[Not yet recruiting]
Pondicherry, Pondy, India, 605007

India, Tamil Nadu

[Not yet recruiting]
Madurai, Tamil Nadu, India, 625020

India, Tamilnadu

[Not yet recruiting]
Chennai, Tamilnadu, India, 600 006

[Not yet recruiting]
Coimbatore, Tamilnadu, India, 641014

India, West Bengal

[Not yet recruiting]
Kolkata, West Bengal, India, 700073

Israel, Be'er Yakov

[Not yet recruiting]
Zrifin, Be'er Yakov, Israel, 70300

Israel

[Recruiting]
Kfar-Saba, Israel, 44281

[Recruiting]
Petah Tikva, Israel, 49100

[Recruiting]

Rehovot, Israel, 76100

[Recruiting]

Tel Aviv, Israel, 64239

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	◉	◉	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: December 3, 2009 (v4)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	December 2009
Overall Status:	Recruiting
Study Start:	July 2009
Primary Completion:	January 2011 [Anticipated]
Study Completion:	August 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	December 3, 2009
Last Update Posted:	December 4, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Central Contact: Irma Alvarez
Telephone: 626-333-3213
Email: irma.alvarez@parexel.com

Central Contact Backup: Heather Evans, BA
Telephone: 914-345-7562
Email: heather.evans@regeneron.com

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

[Recruiting]
Phoenix, Arizona, United States, 85020

[Recruiting]
Tucson, Arizona, United States, 85704

United States, California

[Recruiting]
Beverly Hills, California, United States, 90211

[Recruiting]

Oakland, California, United States, 94609

[Recruiting]

Sacramento, California, United States, 95841

United States, Florida

[Recruiting]

Altamonte Springs, Florida, United States, 32701

[Recruiting]

Fort Myers, Florida, United States, 33907

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46290

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Ann Arbor, Michigan, United States, 48104

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

Northfield, New Jersey, United States, 08225

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Raleigh, North Carolina, United States, 27607

United States, Oregon

[Recruiting]

Portland, Oregon, United States, 97210

United States, South Carolina

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, South Dakota

[Recruiting]

Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Fort Worth, Texas, United States, 76102

[Recruiting]

Houston, Texas, United States, 77030

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	◉	◉	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: October 7, 2009 (v3)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	October 2009
Overall Status:	Recruiting
Study Start:	July 2009
Primary Completion:	January 2011 [Anticipated]
Study Completion:	August 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	October 7, 2009
Last Update Posted:	October 8, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Central Contact: Irma Alvarez
Telephone: 626-333-3213
Email: irma.alvarez@parexel.com

Central Contact Backup: Heather Evans, BA
Telephone: 914-345-7562
Email: heather.evans@regeneron.com

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

[Recruiting]
Phoenix, Arizona, United States, 85020

[Recruiting]
Tucson, Arizona, United States, 85704

United States, California

[Recruiting]
Beverly Hills, California, United States, 90211

[Recruiting]

Oakland, California, United States, 94609

[Recruiting]
Sacramento, California, United States, 95841

United States, Florida

[Recruiting]
Altamonte Springs, Florida, United States, 32701

[Recruiting]
Fort Myers, Florida, United States, 33907

[Recruiting]
Fort Myers, Florida, United States, 33912

[Recruiting]
Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]
Augusta, Georgia, United States, 30909

United States, Indiana

[Recruiting]
Indianapolis, Indiana, United States, 46290

United States, Massachusetts

[Recruiting]
Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]
Ann Arbor, Michigan, United States, 48104

United States, Nebraska

[Recruiting]
Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]

Northfield, New Jersey, United States, 08225

United States, New York

[Recruiting]

Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]

Raleigh, North Carolina, United States, 27607

United States, Oregon

[Recruiting]

Portland, Oregon, United States, 97210

United States, South Carolina

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, South Dakota

[Recruiting]

Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Fort Worth, Texas, United States, 76102

[Recruiting]

Houston, Texas, United States, 77030

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	◉	◉	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: September 3, 2009 (v2)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	September 2009
Overall Status:	Recruiting
Study Start:	July 2009
Primary Completion:	January 2011 [Anticipated]
Study Completion:	August 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	September 3, 2009
Last Update Posted:	September 4, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Central Contact: Suzanne Bates, RN
Telephone: 804-443-3656
Email: suzanne.bates@parexel.com

Central Contact Backup: Heather Evans, BA
Telephone: 914-345-7562
Email: heather.evans@regeneron.com

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

[Recruiting]
Phoenix, Arizona, United States, 85020

[Recruiting]
Tucson, Arizona, United States, 85704

United States, California

[Recruiting]
Beverly Hills, California, United States, 90211

[Recruiting]

Oakland, California, United States, 94609

United States, Florida

[Recruiting]
Altamonte Springs, Florida, United States, 32701

[Recruiting]
Fort Myers, Florida, United States, 33907

[Recruiting]
Fort Myers, Florida, United States, 33912

[Recruiting]
Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]
Augusta, Georgia, United States, 30909

United States, Indiana

[Recruiting]
Indianapolis, Indiana, United States, 46290

United States, Massachusetts

[Recruiting]
Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]
Ann Arbor, Michigan, United States, 48104

United States, Nebraska

[Recruiting]
Lincoln, Nebraska, United States, 68506

United States, South Carolina

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, South Dakota

[Recruiting]

Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Fort Worth, Texas, United States, 76102

[Recruiting]

Houston, Texas, United States, 77030

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	◉	◉	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3062

Samsung Bioepis Exhibit 1017, pg. 3062

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: July 20, 2009 (v1)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	July 2009
Overall Status:	Recruiting
Study Start:	July 2009
Primary Completion:	January 2011 [Anticipated]
Study Completion:	August 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	July 20, 2009
Last Update Posted:	July 21, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Central Contact: Suzanne Bates, RN
Telephone: 804-443-3656
Email: suzanne.bates@parexel.com

Central Contact Backup: Heather Evans, BA
Telephone: 914-345-7562
Email: heather.evans@regeneron.com

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Beverly Hills, California, United States, 90211

United States, Florida

[Recruiting]
Winter Haven, Florida, United States, 33880

United States, Georgia

[Not yet recruiting]
Augusta, Georgia, United States, 30909

United States, Indiana

[Not yet recruiting]
Indianapolis, Indiana, United States, 46290

United States, Massachusetts

[Recruiting]
Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]
Ann Arbor, Michigan, United States, 48104

United States, Nebraska

[Recruiting]
Lincoln, Nebraska, United States, 68506

United States, South Carolina

[Not yet recruiting]
West Columbia, South Carolina, United States, 29169

United States, South Dakota

[Recruiting]
Rapid City, South Dakota, United States, 57701

United States, Texas

[Not yet recruiting]
Fort Worth, Texas, United States, 76102

[Recruiting]
Houston, Texas, United States, 77030

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3070

Samsung Bioepis Exhibit 1017, pg. 3070

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	◉	◉	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: April 16, 2013 (v13)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Official Title: A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion

Secondary IDs:

Study Status

Record Verification: April 2013

Overall Status: Completed

Study Start: July 2009

Primary Completion: October 2010 [Actual]

Study Completion: April 2012 [Actual]

First Submitted: July 10, 2009

First Submitted that Met QC Criteria: July 20, 2009

First Posted: July 21, 2009 [Estimate]

Results First Submitted: October 19, 2012

Results First Submitted that Met QC Criteria:	April 16, 2013
Results First Posted:	May 27, 2013 [Estimate]
Certification/Extension First Submitted:	May 9, 2011
Certification/Extension First Submitted that Met QC Criteria:	May 9, 2011
Certification/Extension First Posted:	May 16, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	April 16, 2013
Last Update Posted:	May 27, 2013 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 189 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

[See Results Section]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)

- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Study Officials: Clinical Trial Management
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Arcadia, California, United States, 91007

Beverly Hills, California, United States, 90211

La Jolla, California, United States, 92037

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Sacramento, California, United States, 95841

Torrance, California, United States, 90503

United States, Connecticut

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33907

Fort Myers, Florida, United States, 33912

Miami, Florida, United States, 33143

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Chicago, Illinois, United States, 60612

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Maryland

Baltimore, Maryland, United States, 21209

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 48104

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, Nevada

Las Vegas, Nevada, United States, 89135

United States, New Jersey

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08755

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cleveland, Ohio, United States, 44195

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Ft Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4V2

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M4N 3M5

Colombia, Antioquia

Medellin, Antioquia, Colombia

Colombia

Bogota, Colombia

India, A.p.

Hyderabad, A.p., India, 500034

India, Karnataka

Bangalore, Karnataka, India, 560010

India, West Bengal

Kolkata, West Bengal, India, 700073

Israel

Kfar-Saba, Israel, 44281

Petah Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 55 study centers in the United States, Canada, Columbia, India, and Israel. The recruitment period occurred between 08 Jul 2009 and 29 Apr 2010.
Pre-assignment Details	273 participants were screened, 189 randomized, and 188 were included in the Safety Analysis Set (SAF). The Full Analysis Set (FAS) included 187 participants with at least one post-baseline assessment.

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Participants received a 2 mg Intravitreal Aflibercept Injection (IAI) every 4 weeks (2Q4) from Baseline (Day 1) to Week 24. Starting at week 24 through week 52, participants were evaluated monthly to receive either the 2 mg IAI PRN or sham injection according to the protocol re-treatment criteria as assessed by the masked physician. If none of the re-treatment criteria were met, participants received a sham injection. From Week 52 to 100, participants were evaluated every three months, but could receive injections of IAI up to monthly if re-treatment criteria were met; sham injections were not given. Participants were observed from Week 24 to Week 100. Participants in the safety population that completed Week 24 were at risk.

Sham Treatment	Participants received sham treatment every 4 weeks from Baseline (Day 1) to Week 24. Starting at week 24 through week 52, participants were eligible for active treatment and were evaluated monthly to receive either 2 mg IAI PRN or sham injection according to the protocol re-treatment criteria as assessed by the masked physician. From Week 52 to 100, participants were evaluated every three months, but could receive injections of IAI up to monthly if re-treatment criteria were met; sham injections were not given.

Overall Study

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment
Started	115	74
Participants Received Treatment	114 [1]	74
Full Analysis Set (FAS) Population	114 [2]	73
Completed	110 [3]	60 [4]
Not Completed	5	14
Adverse Event	0	3
Death	0	2
Withdrawal by Subject	3	1
Protocol Violation	0	1
Lost to Follow-up	1	2
Lack of Efficacy	0	4
Other	1	1

[1] Safety population (SAF)

[2] FAS population used for analysis of Primary and Secondary Outcome Measures

[3] 110 Participants completed Week 24, From FAS; 102 Participants completed up to Week 100, From SAF

[4] 60 Participants completed Week 24, From FAS; 50 Participants completed up to Week 100, From SAF

Baseline Characteristics

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Participants received a 2 mg Intravitreal Aflibercept Injection (IAI) every 4 weeks (2Q4) from Baseline (Day 1) to Week 24.
Sham Treatment	Participants received sham treatment every 4 weeks from Baseline (Day 1) to Week 24.

Baseline Measures

		Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment	Total
Overall Number of Participants		114	74	188
Age Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	114 Participants	74 Participants	188 Participants
		65.5 (13.57)	67.5 (14.22)	66.3 (13.83)
Sex: Female, Male Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	114 Participants	74 Participants	188 Participants
	Female	45 39.47%	35 47.3%	80 42.55%
	Male	69 60.53%	39 52.7%	108 57.45%

		Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment	Total
Ethnicity (NIH/OMB) Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	114 Participants	74 Participants	188 Participants
	Hispanic or Latino	18 15.79%	12 16.22%	30 15.96%
	Not Hispanic or Latino	96 84.21%	62 83.78%	158 84.04%
	Unknown or Not Reported	0 0%	0 0%	0 0%
Race (NIH/OMB) Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	114 Participants	74 Participants	188 Participants
	American Indian or Alaska Native	2 1.75%	0 0%	2 1.06%
	Asian	7 6.14%	2 2.7%	9 4.79%
	Native Hawaiian or Other Pacific Islander	0 0%	1 1.35%	1 0.53%
	Black or African American	5 4.39%	5 6.76%	10 5.32%
	White	88 77.19%	60 81.08%	148 78.72%

		Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment	Total
	More than one race	12 10.53%	6 8.11%	18 9.57%
	Unknown or Not Reported	0 0%	0 0%	0 0%
Baseline Retinal Thickness by Optical Coherence Tomography (OCT)	Number Analyzed	114 Participants	74 Participants	188 Participants
Mean (Standard Deviation) Unit of measure: microns		661.7 (237.37)	678.4 (248.66)	668.1 (241.23)
Baseline National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score [1]	Number Analyzed	114 Participants	74 Participants	188 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		77.67 (15.96)	78.01 (16.26)	77.81 (16.04)
		[1] Measure Description: The NEI VFQ-25 total score ranges from 0-100 with a score of 0 being the worst outcome and 100 being the best outcome. The NEI VFQ questionnaire is organized as a collection of subscales which are all scored from 0-100. To reach the overall composite score, each sub-scale score is averaged in order to give each sub-scale equal weight.		

		Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment	Total
Baseline Intraocular Pressure Mean (Standard Deviation) Unit of measure: millimeters of mercury (mmHg)	Number Analyzed	114 Participants	74 Participants	188 Participants
		15.1 (3.26)	15.0 (2.83)	15.1 (3.09)
Number of Participants with Retinal Perfusion at Baseline [1] Measure type: Number Unit of measure: participants	Number Analyzed	114 Participants	74 Participants	188 Participants
Perfused		77 67.54%	50 67.57%	127 67.55%
Non-Perfused		17 14.91%	12 16.22%	29 15.43%
Indeterminate		20 17.54%	12 16.22%	32 17.02%

[1] Measure Description:

Retinal Perfusion defined as less than 10 disc areas of capillary non-perfusion using fluorescein angiography (FA).

Non-Perfused defined as greater than or equal to 10 disc areas of non-perfusion.

Indeterminate defined as not able to be determined by the reading center; for the purposes of analysis, indeterminate patients were considered non-perfused.

		Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment	Total
Baseline Best Corrected Visual Acuity (BCVA) Letter Score [1] Mean (Standard Deviation) Unit of measure: letters correctly read	Number Analyzed	114 Participants	74 Participants	188 Participants
		50.7 (13.90)	48.7 (14.41)	49.9 (14.10)
		[1] Measure Description: Only participants with an ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.		
Time Since Central Retinal Vein Occlusion (CRVO) Diagnosis Measure type: Number Unit of measure: participants	Number Analyzed	114 Participants	74 Participants	188 Participants
</= 2 Months		64 56.14%	53 71.62%	117 62.23%
> 2 Months		49 42.98%	21 28.38%	70 37.23%
Missing		1 0.88%	0 0%	1 0.53%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters in BCVA at Week 24 as Measured by ETDRS Letter Score
Measure Description	Percentage values indicate the number of subjects in each arm who were able to read an additional 15 letters or more at Week 24 compared to baseline. Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 24 letters (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.
Time Frame	Baseline and at Week 24

Analysis Population Description

Full Analysis Set

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Participants received a 2 mg Intravitreal Aflibercept Injection (IAI) every 4 weeks (2Q4) from Baseline (Day 1) to Week 24.
Sham Treatment	Participants received sham treatment every 4 weeks from Baseline (Day 1) to Week 24.

Measured Values

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment
Overall Number of Participants Analyzed	114	73
Percentage of Participants Who Gained at Least 15 Letters in BCVA at Week 24 as Measured by ETDRS Letter Score Measure Type: Number Unit of Measure: percentage of participants	64	9

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters in BCVA at Week 24 as Measured by ETDRS Letter Score

Statistical Analysis Overview	Comparison Groups	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye), Sham Treatment
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	< 0.0001
	Comments	P-value for the primary endpoint was calculated using 2-sided Cochran-Mantel-Haenszel test adjusted by regions (North America vs. Rest of World) and baseline BCVA (BCVA > 20/200 and BCVA ≤ 20/200)
	Method	Cochran-Mantel-Haenszel
	Comments	CMH adjusted difference

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	44.8
	Confidence Interval	(2-sided) 95% 33.0 to 56.6
	Estimation Comments	The Risk Difference (RD) indicates the difference between the IAI (EYLEA, VEGF Trap-Eye) Treatment group minus the Sham Treatment group.

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in BCVA as Measured by ETDRS Letter Score at Week 24 - Last Observation Carried Forward (LOCF)
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 24 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.
Time Frame	Baseline and at Week 24

Analysis Population Description

Full Analysis Set

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Participants received a 2 mg Intravitreal Aflibercept Injection (IAI) every 4 weeks (2Q4) from Baseline (Day 1) to Week 24.
Sham Treatment	Participants received sham treatment every 4 weeks from Baseline (Day 1) to Week 24.

Measured Values

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment
Overall Number of Participants Analyzed	114	73
Change From Baseline in BCVA as Measured by ETDRS Letter Score at Week 24 - Last Observation Carried Forward (LOCF) Measure Type: Mean (Standard Deviation) Unit of Measure: letters correctly read	17.3 (12.78)	-4.0 (17.96)

Statistical Analysis 1 for Change From Baseline in BCVA as Measured by ETDRS Letter Score at Week 24 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye), Sham Treatment
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	< 0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	21.70
	Confidence Interval	(2-sided) 95% 17.36 to 26.04
	Estimation Comments	RD is the IAI group minus sham group. 95% confidence interval is for the RD.

Statistical Analysis 2 for Change From Baseline in BCVA as Measured by ETDRS Letter Score at Week 24 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye), Sham Treatment
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Least Square Mean
	Estimated Value	16.36

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Central Retinal Thickness (CRT) at Week 24 - LOCF

Measure Description	
Time Frame	Baseline and at Week 24

Analysis Population Description

Full Analysis Set

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Participants received a 2 mg Intravitreal Aflibercept Injection (IAI) every 4 weeks (2Q4) from Baseline (Day 1) to Week 24.
Sham Treatment	Participants received sham treatment every 4 weeks from Baseline (Day 1) to Week 24.

Measured Values

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment
Overall Number of Participants Analyzed	114	73
Change From Baseline in Central Retinal Thickness (CRT) at Week 24 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: microns	-457.2 (238.21)	-144.8 (291.07)

Statistical Analysis 1 for Change From Baseline in Central Retinal Thickness (CRT) at Week 24 - LOCF

Statistical Analysis Overview	Comparison Groups	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye), Sham Treatment
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	< 0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-311.9
	Confidence Interval	(2-sided) 95% -389.4 to -234.4
	Estimation Comments	The Risk Difference (RD) indicates the difference between the IAI (EYLEA, VEGF Trap-Eye) Treatment group minus the Sham Treatment group. 95% confidence interval is for the RD.

Statistical Analysis 2 for Change From Baseline in Central Retinal Thickness (CRT) at Week 24 - LOCF

Statistical Analysis Overview	Comparison Groups	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye), Sham Treatment
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Least Square Mean
	Estimated Value	-487.1

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants Progressing to Any of the Following: Anterior Segment Neovascularization, New Vessels of the Disc (NVD) or New Vessels Elsewhere (NVE) During the First 24 Weeks
Measure Description	
Time Frame	Baseline to Week 24

Analysis Population Description

Full Analysis Set

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Participants received a 2 mg Intravitreal Aflibercept Injection (IAI) every 4 weeks (2Q4) from Baseline (Day 1) to Week 24.
Sham Treatment	Participants received sham treatment every 4 weeks from Baseline (Day 1) to Week 24.

Measured Values

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment
Overall Number of Participants Analyzed	114	73
Percentage of Participants Progressing to Any of the Following: Anterior Segment Neovascularization, New Vessels of the Disc (NVD) or New Vessels Elsewhere (NVE) During the First 24 Weeks Measure Type: Number Unit of Measure: percentage of participants		
Any neovascularization	0	6.8
Anterior segment neovascularization	0	6.8
Neovascularization of the optic disc (NVD)	0	0
Neovascularization elsewhere in the fundus (NVE)	0	0

Statistical Analysis 1 for Percentage of Participants Progressing to Any of the Following: Anterior Segment Neovascularization, New Vessels of the Disc (NVD) or New Vessels Elsewhere (NVE) During the First 24 Weeks

Statistical Analysis Overview	Comparison Groups	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye), Sham Treatment
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0059
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	CMH adjusted difference

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-6.6
	Confidence Interval	(2-sided) 95% -12.2 to -1.1
	Estimation Comments	The Risk Difference (RD) indicates the difference between the IAI (EYLEA, VEGF Trap-Eye) Treatment group minus the Sham Treatment group. 95% confidence interval is for the RD.

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in the NEI VFQ-25 in Total Score at Week 24 (LOCF)
Measure Description	The NEI VFQ-25 assesses visual function and quality of life. Total score ranges from 0-100 with a score of 0 being the worst outcome and 100 being the best outcome. The NEI VFQ questionnaire is organized as a collection of subscales which are all scored from 0-100. To reach the overall composite score, each sub-scale score is averaged in order to give each sub-scale equal weight.
Time Frame	Baseline and at Week 24

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Participants received a 2 mg Intravitreal Aflibercept Injection (IAI) every 4 weeks (2Q4) from Baseline (Day 1) to Week 24.
Sham Treatment	Participants received sham treatment every 4 weeks from Baseline (Day 1) to Week 24.

Measured Values

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Sham Treatment
Overall Number of Participants Analyzed	114	73
Change From Baseline in the NEI VFQ-25 in Total Score at Week 24 (LOCF) Measure Type: Mean (Standard Deviation) Unit of Measure: scores on a scale	7.2 (12.11)	0.8 (9.79)

Statistical Analysis 1 for Change From Baseline in the NEI VFQ-25 in Total Score at Week 24 (LOCF)

Statistical Analysis Overview	Comparison Groups	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye), Sham Treatment
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0009
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	6.26
	Confidence Interval	(2-sided) 95% 2.61 to 9.91
	Estimation Comments	The Risk Difference (RD) indicates the difference between the IAI (EYLEA, VEGF Trap-Eye) Treatment group minus the Sham Treatment group. 95% confidence interval is for the RD.

Statistical Analysis 2 for Change From Baseline in the NEI VFQ-25 in Total Score at Week 24 (LOCF)

Statistical Analysis Overview	Comparison Groups	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye), Sham Treatment
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Least Square Mean
	Estimated Value	8.80

Reported Adverse Events

Time Frame	Baseline to Week 24; Week 24 to Week 100
Adverse Event Reporting Description	Adverse event data were collected from the sites during the time period from Baseline through Week 24 or/and Week 100. For analysis, adverse events with a start date on or after the Week 24 visit date are summarized in the Week 24 to Week 100 time period.

Reporting Groups

	Description
Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Participants received a 2 mg Intravitreal Aflibercept Injection (IAI) every 4 weeks (2Q4) from Baseline (Day 1) to Week 20. Participants were observed until Week 24. Participants in the safety population were at risk.
Sham Treatment (Baseline to Week 24)	Participants received sham treatment every 4 weeks from Baseline (Day 1) to Week 20. Participants were observed until Week 24. Participants in the safety population were at risk.

IAI to IAI (Week 24 to Week 100)	Starting at week 24 through week 52, participants were evaluated monthly to receive either the 2 mg Intravitreal Aflibercept Injection (IAI) PRN or sham injection according to the protocol re-treatment criteria as assessed by the masked physician. If none of the re-treatment criteria were met, participants received a sham injection. From Week 52 to 100, participants were evaluated every three months, but could receive injections of IAI up to monthly if re-treatment criteria were met; sham injections were not given. Participants were observed from Week 24 to Week 100. Participants in the safety population that completed Week 24 were at risk.
Sham Treatment to IAI (Week 24 to Week 100)	Starting at week 24 through week 52, participants were eligible for active treatment and were evaluated monthly to receive either 2 mg Intravitreal Aflibercept Injection (IAI) PRN or sham injection according to the protocol re-treatment criteria as assessed by the masked physician. From Week 52 to 100, participants were evaluated every three months, but could receive injections of IAI up to monthly if re-treatment criteria were met; sham injections were not given.

All-Cause Mortality

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/114 (5.26%)	6/74 (8.11%)	20/110 (18.18%)	14/60 (23.33%)
Blood and lymphatic system disorders				
Anaemia [A*]	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Neutropenia [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Pernicious anaemia [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Cardiac disorders				
Acute myocardial infarction [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)
Aortic valve stenosis [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Atrial fibrillation [A*]	1/114 (0.88%)	0/74 (0%)	1/110 (0.91%)	1/60 (1.67%)
Atrial tachycardia [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Atrioventricular block [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Cardiac failure acute [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Coronary artery disease [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Coronary artery stenosis [A*]	0/114 (0%)	0/74 (0%)	2/110 (1.82%)	0/60 (0%)
Myocardial infarction [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Supraventricular tachycardia [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Ventricular extrasystoles [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Eye disorders				
Cataract [A] [1]*	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Conjunctival haemorrhage [A] [1]*	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Cystoid macular oedema [A] [2]*	0/114 (0%)	0/74 (0%)	2/110 (1.82%)	0/60 (0%)
Dry eye [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Eye irritation [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Eye pain [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Glaucoma [A] [2]*	0/114 (0%)	2/74 (2.7%)	0/110 (0%)	1/60 (1.67%)
Iris neovascularisation [A] [2]*	0/114 (0%)	2/74 (2.7%)	0/110 (0%)	0/60 (0%)
Lacrimation increased [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Macular fibrosis [A] [1]*	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Macular oedema [A] [2]*	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Maculopathy [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Optic disc vascular disorder [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Posterior capsule opacification [A] [1]*	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Retinal artery occlusion [A] [2]*	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Retinal exudates [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Retinal haemorrhage [A] [1]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Retinal pigment epitheliopathy [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Retinal tear [A] [2]*	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	1/60 (1.67%)
Retinal vascular disorder [A] [2]*	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Retinal vein occlusion [A] [2]*	0/114 (0%)	1/74 (1.35%)	1/110 (0.91%)	0/60 (0%)
Visual acuity reduced [A] [2]*	1/114 (0.88%)	1/74 (1.35%)	1/110 (0.91%)	0/60 (0%)
Vitreous detachment [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Vitreous floaters [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Vitreous haemorrhage [A] [1]*	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Gastrointestinal disorders				
Abdominal adhesions [A]*	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Colitis [A]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Dysphagia [A]*	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Gastrointestinal motility disorder [A]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Inguinal hernia [A]*	0/114 (0%)	0/74 (0%)	2/110 (1.82%)	0/60 (0%)
Intestinal ischaemia [A]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Intestinal obstruction [A]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Pancreatitis [A]*	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	1/60 (1.67%)
Small intestinal obstruction [A]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
General disorders				
Adhesion [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Chest discomfort [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Chest pain [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Generalised oedema [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Hepatobiliary disorders				
Bile duct stone [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Cholecystitis [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)
Infections and infestations				
Arthritis bacterial [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Bacteriuria [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Bronchitis [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Bronchitis viral [A*]	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Cellulitis [A*]	0/114 (0%)	1/74 (1.35%)	1/110 (0.91%)	0/60 (0%)
Clostridial infection [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)
Endophthalmitis [A [2]*]	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Herpes oesophagitis [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Influenza [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Nasopharyngitis [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Periorbital cellulitis [A [1]*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Pneumonia [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	3/60 (5%)
Upper respiratory tract infection [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Urinary tract infection [A*]	0/114 (0%)	0/74 (0%)	2/110 (1.82%)	0/60 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	1/60 (1.67%)
Brain contusion [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Corneal abrasion [A [2]*]	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Craniocerebral injury [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Facial bones fracture [A [1]*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Fall [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Femur fracture [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
In-stent coronary artery restenosis [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Radius fracture [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Renal haematoma [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Skull fracture [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Spinal column injury [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Investigations				
Blood pressure systolic increased [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Blood urine present [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Intraocular pressure increased [A [1]*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Protein urine present [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Metabolism and nutrition disorders				
Abnormal loss of weight [A*]	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Dehydration [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Hypokalaemia [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Musculoskeletal and connective tissue disorders				
Arthritis [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	1/60 (1.67%)
Intervertebral disc degeneration [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Intervertebral disc protrusion [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Osteoarthritis [A*]	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Colon cancer [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	1/60 (1.67%)
Mantle cell lymphoma [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Metastatic renal cell carcinoma [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Non-small cell lung cancer [A*]	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Oesophageal adenocarcinoma stage IV [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)
Prostate cancer [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)
Squamous cell carcinoma of skin [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Thyroid cancer [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)
Nervous system disorders				
Carotid artery stenosis [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)
Convulsion [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Dementia [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Encephalopathy [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Haemorrhagic cerebral infarction [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Loss of consciousness [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Subarachnoid haemorrhage [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Syncope [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Psychiatric disorders				
Mental status changes [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Renal and urinary disorders				
Haematuria [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Obstructive uropathy [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Renal failure acute [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	2/60 (3.33%)
Renal failure chronic [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Cystocele [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Rectocele [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Respiratory, thoracic and mediastinal disorders				
Apnoea [A*]	0/114 (0%)	1/74 (1.35%)	0/110 (0%)	0/60 (0%)
Asthma [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Epistaxis [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Pneumonia aspiration [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)
Pneumothorax [A*]	1/114 (0.88%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Respiratory failure [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	1/60 (1.67%)
Skin and subcutaneous tissue disorders				
Dermatitis contact [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Vascular disorders				
Hypertension [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Hypotension [A*]	0/114 (0%)	0/74 (0%)	1/110 (0.91%)	0/60 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA Version 13.1

[1] Ocular AE Fellow Eye

[2] Ocular AE Study Eye

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	57/114 (50%)	34/74 (45.95%)	76/110 (69.09%)	50/60 (83.33%)
Eye disorders				
Cataract [A [1]*]	0/114 (0%)	0/74 (0%)	6/110 (5.45%)	0/60 (0%)
Cystoid macular oedema [A [2]*]	0/114 (0%)	0/74 (0%)	14/110 (12.73%)	4/60 (6.67%)
Dry eye [A [2]*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	4/60 (6.67%)
Eye irritation [A [2]*]	6/114 (5.26%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Eye pain [A [2]*]	16/114 (14.04%)	4/74 (5.41%)	9/110 (8.18%)	4/60 (6.67%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Iris neovascularisation [A] [2]*	0/114 (0%)	4/74 (5.41%)	0/110 (0%)	0/60 (0%)
Lacrimation increased [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	4/60 (6.67%)
Macular oedema [A] [2]*	0/114 (0%)	0/74 (0%)	20/110 (18.18%)	0/60 (0%)
Maculopathy [A] [2]*	10/114 (8.77%)	0/74 (0%)	6/110 (5.45%)	0/60 (0%)
Optic disc vascular disorder [A] [2]*	8/114 (7.02%)	0/74 (0%)	6/110 (5.45%)	5/60 (8.33%)
Retinal exudates [A] [2]*	7/114 (6.14%)	0/74 (0%)	0/110 (0%)	5/60 (8.33%)
Retinal haemorrhage [A] [1]*	0/114 (0%)	0/74 (0%)	6/110 (5.45%)	4/60 (6.67%)
Retinal pigment epitheliopathy [A] [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	12/60 (20%)
Retinal vascular disorder [A] [2]*	6/114 (5.26%)	4/74 (5.41%)	8/110 (7.27%)	0/60 (0%)
Visual acuity reduced [A] [2]*	7/114 (6.14%)	12/74 (16.22%)	27/110 (24.55%)	8/60 (13.33%)
Vitreous detachment [A] [2]*	0/114 (0%)	5/74 (6.76%)	8/110 (7.27%)	0/60 (0%)
Vitreous floaters [A] [2]*	6/114 (5.26%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Infections and infestations				
Influenza [A]*	0/114 (0%)	0/74 (0%)	7/110 (6.36%)	0/60 (0%)
Nasopharyngitis [A]*	0/114 (0%)	4/74 (5.41%)	6/110 (5.45%)	0/60 (0%)
Upper respiratory tract infection [A]*	6/114 (5.26%)	0/74 (0%)	6/110 (5.45%)	0/60 (0%)
Investigations				
Blood pressure systolic increased [A]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	4/60 (6.67%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Blood urine present [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	4/60 (6.67%)
Intraocular pressure increased [A] [1]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	4/60 (6.67%)
Protein urine present [A*]	0/114 (0%)	0/74 (0%)	0/110 (0%)	5/60 (8.33%)
Vascular disorders				
Hypertension [A*]	10/114 (8.77%)	4/74 (5.41%)	13/110 (11.82%)	9/60 (15%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA Version 13.1

[1] Ocular AE Fellow Eye

[2] Ocular AE Study Eye

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Clinical Trials Administrator
Organization: Regeneron Pharmaceuticals
Phone: 914 847 5385
Email: clinicaltrials@regeneron.com

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	○	○	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	◉	◉	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: June 7, 2012 (v12)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	June 2012
Overall Status:	Completed
Study Start:	July 2009
Primary Completion:	October 2010 [Actual]
Study Completion:	April 2012 [Actual]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Certification/Extension First Submitted:	May 9, 2011
Certification/Extension First Submitted that Met QC Criteria:	May 9, 2011
Certification/Extension First Posted:	May 16, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	June 7, 2012
Last Update Posted:	June 11, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.
Detailed Description:	

Conditions

Conditions:	Macular Edema Secondary to Central Retinal Vein Occlusion
Keywords:	Macular edema Retinal vein occlusion CRVO VEGF Trap-Eye best-corrected visual acuity Regeneron COPERNICUS

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 189 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Study Officials: Clinical Trial Management
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Arcadia, California, United States, 91007

Beverly Hills, California, United States, 90211

La Jolla, California, United States, 92037

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Sacramento, California, United States, 95841

Torrance, California, United States, 90503

United States, Connecticut

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33907

Fort Myers, Florida, United States, 33912

Miami, Florida, United States, 33143

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Chicago, Illinois, United States, 60612

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Maryland

Baltimore, Maryland, United States, 21209

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 48104

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, Nevada

Las Vegas, Nevada, United States, 89135

United States, New Jersey

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08755

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cleveland, Ohio, United States, 44195

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Ft Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4V2

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M4N 3M5

Colombia, Antioquia

Medellin, Antioquia, Colombia

Colombia

Bogota, Colombia

India, A.p.

Hyderabad, A.p., India, 500034

India, Karnataka

Bangalore, Karnataka, India, 560010

India, West Bengal

Kolkata, West Bengal, India, 700073

Israel

Kfar-Saba, Israel, 44281

Petah Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 20, 2009	None (earliest Version on record)
2	○	○	September 3, 2009	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 7, 2009	Contacts/Locations and Study Status
4	○	○	December 3, 2009	Study Status
5	○	○	February 18, 2010	Contacts/Locations and Study Status
6	○	○	July 2, 2010	Recruitment Status, Study Status and Contacts/Locations
7	○	○	November 18, 2010	Study Status
8	○	○	February 11, 2011	Study Status and Study Design
9	○	○	May 5, 2011	Study Status
10	○	○	May 9, 2011	Study Status
11	◉	◉	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	○	○	June 7, 2012	Recruitment Status, Study Status
13	○	○	April 16, 2013	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00943072

Submitted Date: March 28, 2012 (v11)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title:	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)
Official Title:	A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion
Secondary IDs:	

Study Status

Record Verification:	March 2012
Overall Status:	Active, not recruiting
Study Start:	July 2009
Primary Completion:	October 2010 [Actual]
Study Completion:	April 2012 [Anticipated]
First Submitted:	July 10, 2009
First Submitted that Met QC Criteria:	July 20, 2009
First Posted:	July 21, 2009 [Estimate]
Certification/Extension First Submitted:	May 9, 2011
Certification/Extension First Submitted that Met QC Criteria:	May 9, 2011
Certification/Extension First Posted:	May 16, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	March 28, 2012
Last Update Posted:	March 30, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.
Detailed Description:	

Conditions

Conditions:	Macular Edema Secondary to Central Retinal Vein Occlusion
Keywords:	Macular edema Retinal vein occlusion CRVO VEGF Trap-Eye best-corrected visual acuity Regeneron COPERNICUS

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 189 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
   Week 24

Secondary Outcome Measures:

2. Visual acuity
   Week 24
3. Retinal thickness by OCT
   Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Study Officials: Clinical Trial Management
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Arcadia, California, United States, 91007

Beverly Hills, California, United States, 90211

La Jolla, California, United States, 92037

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Sacramento, California, United States, 95841

Torrance, California, United States, 90503

United States, Connecticut

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33907

Fort Myers, Florida, United States, 33912

Miami, Florida, United States, 33143

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Chicago, Illinois, United States, 60612

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Maryland

Baltimore, Maryland, United States, 21209

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 48104

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, Nevada

Las Vegas, Nevada, United States, 89135

United States, New Jersey

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08755

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cleveland, Ohio, United States, 44195

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Ft Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4V2

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M4N 3M5

Colombia, Antioquia

Medellin, Antioquia, Colombia

Colombia

Bogota, Colombia

India, A.p.

Hyderabad, A.p., India, 500034

India, Karnataka

Bangalore, Karnataka, India, 560010

India, West Bengal

Kolkata, West Bengal, India, 700073

Israel

Kfar-Saba, Israel, 44281

Petah Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

FREE

ARVO Annual Meeting Abstract | April 2010

DA VINCI: DME and VEGF Trap-Eye: INvestigation of Clinical Impact: Phase 2 Study in Patients With Diabetic Macular Edema (DME)

J. C. Major, Jr.; D. M. Brown; DA VINCI Study Group

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science April 2010, Vol.51, 6426. doi:

Abstract

Purpose: : VEGF Trap-Eye (VTE) is a recombinant fusion protein consisting of VEGF binding domains of human VEGF receptors 1 and 2 fused to the Fc domain of human IgG1. This phase 2 study assesses the efficacy and safety of intravitreal VTE vs. laser photocoagulation in DME at the 24-week primary endpoint.

Methods: : DA VINCI is a multi-center, randomized, active-controlled Phase 2 clinical study, designed to assess safety and efficacy of 4 dose/dose intervals of VTE in comparison to laser photocoagulation. 221 patients were randomized (219 treated) to 1 of the following treatment arms: 0.5mg q4wks, 2mg q4wks, 2mg q8wks, 2mg prn or laser photocoagulation. The primary endpoint is the mean change from baseline in BCVA at week 24. Secondary endpoints include changes in retinal thickness (CRT) on OCT and central retinal sensitivity. Central retinal sensitivity was measured using the Nidek MP-1 microperimeter with values corresponding to the OCT central subfield.

Results: : At 6 months, the mean change in BCVA for each VTE arm ranged from +8.5 to +11.4 letters and was statistically significantly better than the mean change in BCVA in the laser arm (+2.5 letters; $p<0.01$). No significant difference was noted among the VTE arms. Anatomical effects (mean change in CRT) for each VTE arm ranged from -127µm to -195µm and were significantly greater than the mean change in CRT for the laser arm (-68µm; $p<0.01$). VTE arms had a mean gain in central retinal sensitivity ranging from 1.5 to 4.1dB, while the laser arm had a mean decrease of -0.4dB. VTE was generally well-tolerated, and

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3134

Samsung Bioepis Exhibit 1017, pg. 3134

adverse events (AEs) reported were those typically associated with intravitreal injections or underlying disease. There were two cases of endophthalmitis, one culture negative and one positive for Staphylococcus epidermidis. The most frequent AEs reported in the VTE arm include conjunctival hemorrhage, eye pain, floaters, ocular hyperemia, and increased IOP.

Conclusions: : In this patient population at the 24-week primary endpoint, intravitreal VTE was generally well tolerated and produced significant improvements from baseline in visual acuity and retinal thickness and a trend toward improvement in central retinal sensitivity as compared to laser photocoagulation.

Clinical Trial: : www.clinicaltrials.gov NCT00789477

Keywords: diabetic retinopathy • clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials • vascular endothelial growth factor

© 2010, The Association for Research in Vision and Ophthalmology, Inc., all rights reserved. Permission to republish any abstract or part of an abstract in any form must be obtained in writing from the ARVO Office prior to publication.

FREE

ARVO Annual Meeting Abstract | April 2011

Randomized, Double-masked, Active-controlled Phase 3 Trial Of The Efficacy And Safety Of Intravitreal VEGF Trap-Eye In Wet AMD: One-year Results Of The View-1 Study

Quan D. Nguyen; Jeffery Heier; David Brown; Allen Ho; Peter Kaiser; Robert Vitti; VIEW 1 Study Group

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science April 2011, Vol.52, 3073. doi:

Abstract

Purpose: : To evaluate the efficacy and safety of VEGF Trap-Eye (VTE) vs ranibizumab in patients with choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD).

Methods: : In this non-inferiority study conducted in N. America, 1217 patients were randomized to VTE 0.5 mg every month (4 weeks; 0.5q4wk), 2 mg every month (2q4wk), 2 mg every 2 months (8 weeks; 2q8wk) following 3 monthly doses, or ranibizumab 0.5 mg every month (Rq4wk). The proportion of patients avoiding moderate vision loss (patients losing <15 ETDRS letters) from baseline to week 52 was the primary endpoint. Secondary endpoints included the mean change from baseline in best corrected visual acuity by an ETDRS letter score.

Results: : The proportions of patients maintaining vision at 52 weeks were 94.4%, 95.9%, 95.1%, and 95.1% for Rq4wk, 0.5q4wk, 2q4wk, and 2q8wk, respectively. All VTE groups were non-inferior (non-inferiority margin of 10%) to ranibizumab. Mean improvements from baseline in ETDRS letter score for Rq4wk, 0.5q4wk, 2q4wk and 2q8wk were 8.1, 6.9, 10.9, and 7.9 letters, respectively. 2q4wk was significantly better ($P<0.01$) than Rq4wk; differences between the other VTE groups and Rq4wk were non-significant. The incidences of ocular treatment emergent adverse events (AEs) were similar across all treatments, with

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3136

Samsung Bioepis Exhibit 1017, pg. 3136

the most frequent AEs associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular AEs were conjunctival hemorrhage, macular degeneration, eye pain, vitreous detachment, and vitreous floaters.

Conclusions: : Dosing monthly or every two months with VEGF Trap-Eye was non-inferior to monthly ranibizumab. VEGF Trap-Eye was generally well tolerated and had a generally favorable safety profile. Based upon these results, VEGF Trap-Eye may provide convenient management of wet AMD with predictable, every two month dosing.

Clinical Trial: : http://www.clinicaltrials.gov NCT00509795

Keywords: age-related macular degeneration • vascular endothelial growth factor • clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials

© 2011, The Association for Research in Vision and Ophthalmology, Inc., all rights reserved. Permission to republish any abstract or part of an abstract in any form must be obtained in writing from the ARVO Office prior to publication.

FREE
ARVO Annual Meeting Abstract | May 2006

Results of a Phase I, Dose–Escalation, Safety, Tolerability, and Bioactivity Study of Intravitreous VEGF Trap in Patients With Neovascular Age–Related Macular Degeneration

Q.D. Nguyen; S.M. Shah; D. Browning; P. Sonkin; H. Hudson; K. Chu; K. Rich; A. Lucas; J. Cedarbaum; P.A. Campochiaro

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science May 2006, Vol.47, 2144. doi:

Abstract

Purpose: : To determine the safety, tolerability, maximum tolerated dose, and bioactivity of intravitreous injection of VEGF Trap in patients with neovascular age–related macular degeneration (AMD).

Methods: : Patients with neovascular AMD who had lesions ≤ 12 disc areas in size with at least 50% active choroidal neovascularization and best–corrected visual acuity (VA) of ≤ 20/40 (ETDRS protocol) received a single intravitreous injection of VEGF Trap at day 0. Safety assessments included eye examinations, vital signs, and laboratory tests (hematology, chemistry, urinalysis, levels of VEGF Trap and antibodies directed against VEGF Trap). Measures of bioactivity were changes from baseline in VA, excess foveal thickness and excess macular volume determined by optical coherence tomography, and lesion size and leakage determined by fluorescein angiography. Patients were monitored for 12 weeks following VEGF Trap administration.

Results: : Three patients at each of 4 dose levels, 0.05, 0.15, 0.5, and 1 mg, have been enrolled. There have been no serious adverse events and no identifiable intraocular inflammation. Excess foveal thickness and excess macular volume decreased rapidly after

injection of VEGF Trap. At day 29, excess foveal thickness was reduced by at least 70% in 75% of patients and VA was stable or improved in 75% of patients.

Conclusions: : Intravitreous injection of up to 1 mg of VEGF Trap has been well–tolerated. Although the number of patients in each cohort is small, preliminary evidence of bioactivity in patients with neovascular AMD has been seen. Higher doses are being investigated to identify the ideal dose of VEGF Trap for a phase II trial in patients with neovascular AMD.

Keywords: macula/fovea • choroid: neovascularization • clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials

© 2006, The Association for Research in Vision and Ophthalmology, Inc., all rights reserved. Permission to republish any abstract or part of an abstract in any form must be obtained in writing from the ARVO Office prior to publication.

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-K

Filing Date: 2/27/2008

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2007

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**13-3444607**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No)*
777 Old Saw Mill River Road, Tarrytown, New York	**10591-6707**
(Address of principal executive offices)	*(Zip code)*

(914) 347-7000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock — par value $.001 per share	Nasdaq Global Market

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☑	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $1,112,577,000 computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2007, the last trading day of the registrant's most recently completed second fiscal quarter.

The number of shares outstanding of each of the registrant's classes of common stock as of February 15, 2008:

Class of Common Stock	**Number of Shares**
Class A Stock, $.001 par value	2,257,698
Common Stock, $.001 par value	76,727,047

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2007 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 59 to 61 of this filing.

PART I

Item I. ***Business***

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We currently have four clinical development programs, including three late-stage clinical programs: ARCALYST™(rilonacept; also known as IL-1Trap) in various inflammatory indications, aflibercept (VEGF Trap) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. Aflibercept is being developed in oncology in collaboration with the sanofi-aventis Group. The VEGF Trap-Eye is being developed in collaboration with Bayer HealthCare LLC. Our fourth clinical development program is REGN88, an antibody to the Interleukin-6 receptor (IL-6R) that is being developed with sanofi-aventis. REGN88 entered clinical development in patients with rheumatoid arthritis in the fourth quarter of 2007. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the *VelocImmune* platform which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we moved our first antibody product candidate (REGN88) into clinical trials in the fourth quarter of 2007. We plan to advance two new antibody product candidates into clinical development in 2008 and an additional two to three antibody product candidates each year thereafter beginning in 2009. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Late-Stage Clinical Programs:

1. ***ARCALYST™ — Inflammatory Diseases***

ARCALYST™(rilonacept; also known as IL-1Trap) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating ARCALYST™ in a number of diseases and disorders where IL-1 may play an important role, including a group of

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3142

Samsung Bioepis Exhibit 1017, pg. 3142

rare diseases called Cryopyrin-Associated Periodic Syndromes (CAPS) and other diseases associated with inflammation.

In November 2007, we announced that we received notification from the U.S. Food and Drug Administration (FDA) that the action date for the FDA's priority review of the Biologics License Application (BLA) for ARCALYST™ in CAPS had been extended three months to February 29, 2008. In August 2007, the FDA granted priority review status to the BLA for ARCALYST™ for the long-term treatment of CAPS. The FDA previously granted Orphan Drug status and Fast Track designation to ARCALYST™ for the treatment of CAPS. In July 2007, ARCALYST™ also received Orphan Drug designation in the European Union for the treatment of CAPS.

CAPS represents a group of rare inherited auto-inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). CAPS also includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST™ has not been studied, and is not expected to be indicated, for the treatment of NOMID. The syndromes included in CAPS are characterized by spontaneous, systemic inflammation and are termed auto-inflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as *CIAS1*) which encodes a protein named cryopyrin. Currently, there are no medicines approved for the treatment of CAPS.

We have initiated a Phase 2 safety and efficacy trial of ARCALYST™ in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy used to control the disease. We previously reported positive results from an exploratory proof of concept study of ARCALYST™ in ten patients with chronic active gout. In those patients, treatment with ARCALYST™ demonstrated a statistically significant reduction in patient pain scores in the single-blind, placebo-controlled study. Mean patients' pain scores, the key symptom measure in persistent gout, were reduced 41% ($p=0.025$) during the first two weeks of active treatment and reduced 56% ($p<0.004$) after six weeks of active treatment. In this study, in which safety was the primary endpoint measure, treatment with ARCALYST™ was generally well-tolerated. We are also evaluating the potential use of ARCALYST™in other indications in which IL-1 may play a role.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

Under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our ARCALYST™ product candidate currently in clinical development.

2. Aflibercept (VEGF Trap) — Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis began the first four trials of our global Phase 3 development program in the second half of 2007. One trial is evaluating aflibercept in combination with docetaxel/prednisone in patients with first line metastatic androgen

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3143

Samsung Bioepis Exhibit 1017, pg. 3143

independent prostate cancer. A second trial is evaluating aflibercept in combination with docetaxel in patients with second line metastatic non-small cell lung cancer. The third Phase 3 trial is evaluating aflibercept in first-line metastatic pancreatic cancer in combination with gemcitabine. The fourth Phase 3 trial is evaluating aflibercept in second-line metastatic colorectal cancer in combination with FOLFIRI (Folinic Acid (leucovorin), 5-fluorouracil, and irinotecan). In all of these trials, aflibercept is being combined with the current standard of chemotherapy care for the stated development stage of the cancer type.

The collaboration is conducting a number of other trials in the global development program for aflibercept. Five safety and tolerability studies of aflibercept in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the Phase 3 clinical program. Sanofi-aventis has also expanded the development program to Japan, where they are conducting a Phase 1 safety and tolerability study in combination with another investigational agent in patients with advanced solid malignancies.

The collaboration is also conducting Phase 2 single-agent studies of aflibercept in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). The AOC and NSCLA trials are fully enrolled and ongoing. The SMA trial is approximately 50% enrolled and continues to enroll patients. In 2004, the FDA granted Fast Track designation to aflibercept for the treatment of SMA.

In addition, more than 10 studies are currently underway or scheduled to begin that are being conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

The first registration submission to a regulatory agency for aflibercept is possible as early as 2008, potentially as third line treatment as a single agent in advanced ovarian cancer (AOC) or in AOC patients with SMA. However, in order for our ongoing Phase 2 study in AOC to be sufficient to support such a submission, we believe that the final unblinded results of the study would have to demonstrate a more robust response rate than that reported in the interim analysis of blinded data from the study presented in June 2007 at the annual meeting of the American Society of Clinical Oncology (ASCO).

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). Vascular Endothelial Growth Factor (VEGF) is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth, and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin® (a trademark of Genentech, Inc.) is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

Aflibercept Collaboration with the sanofi-aventis Group

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to $400.0 million in milestone

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3144

Samsung Bioepis Exhibit 1017, pg. 3144

payments upon receipt of specified marketing approvals. This total includes up to $360.0 million in milestone payments related to receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union. Another $40.0 million of milestone payments relate to receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

3. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 3 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and has completed a small pilot study in patients with diabetic macular edema (DME).

In the clinical development program for the VEGF Trap-Eye, we and Bayer HealthCare have initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. This first trial, known as VIEW 1 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), is comparing the VEGF Trap-Eye and Genentech, Inc.'s Lucentis® (ranibizumab), an anti-angiogenic agent approved for use in wet AMD. This Phase 3 trial is evaluating dosing intervals of four and eight weeks for the VEGF Trap-Eye compared with ranibizumab dosed according to its label every four weeks. We and Bayer HealthCare plan to initiate a second Phase 3 trial in wet AMD in 2008. This second trial will be conducted primarily in the European Union and other parts of the world outside the U.S.

In October 2007, we and Bayer HealthCare announced positive results from the full analysis of the primary 12-week endpoint of a Phase 2 study evaluating the VEGF Trap-Eye in wet AMD. The VEGF Trap-Eye met the primary study endpoint of a statistically significant reduction in retinal thickness, a measure of disease activity, after 12 weeks of treatment compared with baseline (all five dose groups combined, mean decrease of 119 microns, $p<0.0001$). The mean change from baseline in visual acuity, a key secondary endpoint of the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.7 letters, $p<0.0001$). Preliminary analyses at 16 weeks showed that the VEGF Trap-Eye, dosed monthly, achieved a mean gain in visual acuity of 9.3 to 10 letters (for the 0.5 and 2 mg dose groups, respectively). In additional exploratory analyses, the VEGF Trap-Eye, dosed monthly, reduced the proportion of patients with vision of 20/200 or worse (a generally accepted definition for legal blindness) from 14.3% at baseline to 1.6% at week 16; the proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) was likewise increased from 19.0% at baseline to 49.2% at 16 weeks. These findings were presented at the Retina Society Conference in September 2007.

We and Bayer HealthCare are also developing the VEGF Trap-Eye in DME. In May 2007, at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), the companies reported results from a small pilot study of the VEGF Trap-Eye in patients with DME. In the study, the VEGF Trap-Eye was well tolerated and demonstrated activity in five patients, with decreases in retinal thickness and improvement in visual acuity.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis® (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3145

Samsung Bioepis Exhibit 1017, pg. 3145

characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of the VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic eye diseases, and other diseases and disorders. Bayer HealthCare will market the VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of the VEGF Trap-Eye. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of $75.0 million from Bayer HealthCare. In 2007, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in wet AMD, and can earn up to $90.0 million in additional development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135.0 million in sales milestones if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200.0 million.

Antibody Research Technologies and Development Program:

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of secreted proteins can have clinical benefit.

Regeneron scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the "Trap" technology, was used to generate our current clinical pipeline, including aflibercept, the VEGF Trap-Eye, and ARCALYST™. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates.

Regeneron scientists also have discovered and developed a new technology for designing protein therapeutics that facilitates the discovery and production of fully human monoclonal antibodies. We call our technology *VelocImmune®*and, as described below, we believe that it is an improved way of generating a wide variety of high affinity, therapeutic, fully human monoclonal antibodies.

VelocImmune® (Human Monoclonal Antibodies)

We have developed a novel mouse technology platform, called *VelocImmune*, for producing fully human monoclonal antibodies. The *VelocImmune* mouse platform was generated by exploiting our *VelociGene* technology platform (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. The *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our related technologies offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3146

Samsung Bioepis Exhibit 1017, pg. 3146

candidates for preclinical development and are exploring possible additional licensing or collaborative arrangements with third parties related to *VelocImmune* and related technologies.

Antibody Collaboration with the sanofi-aventis Group

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The first therapeutic antibody to enter clinical development under the collaboration, REGN88, is an antibody to the Interleukin-6 receptor (IL-6R), which has started clinical trials in rheumatoid arthritis. The second is expected to be an antibody to Delta-like ligand-4 (Dll4) which is currently scheduled to commence clinical development in mid-2008. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis will fund up to $475.0 million of our research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against these targets through December 31, 2012. Sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis funding drug candidate development costs up front. We are responsible for reimbursing sanofi-aventis for half of the total development costs it paid for all collaboration products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

License Agreement with AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million non-refundable, up-front payment to us. AstraZeneca is required to make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

License Agreement with Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million non-refundable, up-front payment to us. Astellas is required to make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

VelociGene® and VelociMouse™ (Target Validation)

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene and accelerates the production of knock-out and transgenic

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3147

Samsung Bioepis Exhibit 1017, pg. 3147

expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker is substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body, during normal body functioning, as well as in disease processes. For the optimization of pre-clinical development and toxicology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

The *VelociMouse* technology also allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, Regeneron's *VelociMice* are suitable for direct phenotyping or other studies.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We use our *VelociGene* technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our *VelociGene* technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse ES cells which can be used to produce knockout mice. These materials will be made widely available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, we are entitled to receive a minimum of $17.9 million over a five-year period. We will receive another $1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Cell Line Expression Technologies

Many proteins that are of potential pharmaceutical value are proteins which are "secreted" from the cells into the bloodstream. Examples of secreted proteins include growth factors (such as insulin and growth hormone) and antibodies. Current technologies for the isolation of cells engineered to produce high levels of secreted proteins are both laborious and time consuming. We have developed enabling platforms for the high-throughput, rapid generation of high-producing cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

Research Programs:

Oncology and Angiogenesis

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In 1994, we discovered a second family of angiogenic growth factors, termed Angiopoietins, and we have received patents covering members of this family. Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. Angiopoietins are being evaluated in preclinical research by us and our academic collaborators. Our preclinical studies have revealed that VEGF and Angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Manipulation of both VEGF and Angiopoietins seems to be of value in blocking vessel growth. We have research programs focusing on several targets in the areas of oncology and angiogenesis.

Tumors depend on the growth of new blood vessels (a process called "angiogenesis") to support their continued growth. Therapies that block tumor angiogenesis, specifically those that block VEGF, the key initiator of

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3148

Samsung Bioepis Exhibit 1017, pg. 3148

tumor angiogenesis, recently have been validated in human cancer patients. However, anti-VEGF approaches do not work in all patients, and many tumors can become resistant to such therapies.

In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like Ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. We plan in mid-2008 to commence Phase 1 clinical development of a fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune* technology.

Metabolic and Related Diseases

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in integrating peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program in this area encompasses the study of peripheral (hormonal) regulators of food intake and metabolism in health and disease. We have identified several targets in these therapeutic areas and are evaluating potential antibodies to evaluate in preclinical studies.

Muscle Diseases and Disorders

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle research program is currently focused on conducting in vivo and in vitro experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. We have several molecules in late stage research and are evaluating them for possible further development.

Other Therapeutic Areas

We also have research programs focusing on ophthalmology, inflammatory and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Manufacturing

In 1993, we purchased our 104,000 square foot Rensselaer, New York manufacturing facility, and in 2003 completed a 19,500 square foot expansion of this facility. This facility is used to manufacture therapeutic candidates for our own preclinical and clinical studies. We also used the facility to manufacture a product for Merck & Co., Inc. under a contract that expired in October 2006. In July 2002, we leased 75,000 square feet in a building near our Rensselaer facility which we have used primarily for the manufacture of Traps and for warehouse space. In June 2007, we exercised a purchase option on this building, which totals 272,000 square feet (including the 75,000 square feet we already leased), and completed the purchase of this property in October 2007. At December 31, 2007, we employed 207 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2007.

Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the good manufacturing practice (GMP) regulations of the health authority. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies. If our manufacturing facilities fail

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3149

Samsung Bioepis Exhibit 1017, pg. 3149

to comply with FDA and other regulatory requirements, we will be required to suspend manufacturing. This would likely have a material adverse effect on our financial condition, results of operations, and cash flow.

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies (see "Risk Factors — *Even if our product candidates are approved for marketing their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.*"). Our competitors include Genentech, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Abbott Laboratories, sanofi-aventis, Merck, Amgen Inc., Roche, and others. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also be significant if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, one or more of our competitors may achieve product commercialization earlier than we do or obtain patent protection that dominates or adversely affects our activities. Our ability to compete will depend on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

ARCALYST™. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex Corporation), Remicade® (Centocor, Inc.), and Humira® (Abbott) and the IL-1 receptor antagonist Kineret (Amgen), and other marketed therapies, makes it difficult to successfully develop and commercialize ARCALYST™. Even if ARCALYST™ is ever approved for sale, it will be difficult for our drug to compete against these FDA approved drugs because doctors and patients will have significant experience using these effective medicines. Moreover, there are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company, Novartis, and Xoma Ltd. are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over ARCALYST™. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYST™.

Aflibercept and VEGF Trap-Eye. Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to our VEGF Trap in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate.

In particular, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and a number of pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Pfizer, and Imclone Systems Incorporated. Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3150

Samsung Bioepis Exhibit 1017, pg. 3150

modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The National Eye Institute plans to initiate a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. Avastin is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other areas.

REGN88. We are developing REGN88 for the treatment of rheumatoid arthritis as part of our global, strategic collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott), and other marketed therapies makes it difficult to successfully develop and commercialize REGN88. REGN88 is a human monoclonal antibody targeting the interleukin-6 receptor. Roche is developing an antibody against the interleukin-6 (IL-6) receptor. Roche's antibody has completed Phase 3 clinical trials and is the subject of a filed Biologics License Application with the FDA for the treatment of rheumatoid arthritis. Roche's IL-6 receptor antibody, other clinical candidates in development, and the drugs on the market to treat rheumatoid arthritis could offer competitive advantages over REGN88. This could delay or impair our ability to successfully develop and commercialize REGN88.

Other Areas. Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics that are the focus of other research or development programs we are now conducting. These competitors include Amgen and Genentech, as well as many others. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

If a competitor announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, the announcement may have an adverse effect on our operations or future prospects or on the market price of our Common Stock.

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties or other consideration for use of their technology. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see "Risk Factors — *We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.*"). Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. We are the nonexclusive licensee of a number of additional U.S. patents and patent applications. We also rely upon trade secrets, know-how, and continuing technological innovation in an effort to develop and maintain our competitive position. We or our licensors or collaborators have filed patent applications on various products and processes relating to our product candidates as well as other technologies and inventions in the United States and in certain foreign countries. We intend to file additional patent applications, when appropriate, relating to improvements in

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3151

Samsung Bioepis Exhibit 1017, pg. 3151

these technologies and other specific products and processes. We plan to aggressively prosecute, enforce, and defend our patents and other proprietary technology.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process patent applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of our product candidates (see "Risk Factors — *If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.*"). All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase 3, large-scale clinical trials are conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a Biologics License Application, or BLA, for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3152

Samsung Bioepis Exhibit 1017, pg. 3152

Various federal, state, and foreign statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, and other aspects of pharmaceutical product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

In addition to the foregoing, our present and future business will be subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations.

Business Segments

Through 2006, our operations were managed in two business segments: research and development, and contract manufacturing. The research and development segment includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. It also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and our grant from the NIH, and (ii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology. The contract manufacturing segment included all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006 and 2005, the Company manufactured a product for Merck under a contract that expired in October 2006. For financial information about these segments, see Note 20, "Segment Information", beginning on page F-36 in our Financial Statements. Due to the expiration of our manufacturing agreement with Merck, beginning in 2007, we only have a research and development business segment.

Employees

As of December 31, 2007, we had 682 full-time employees, of whom 107 held a Ph.D. or M.D. degree or both. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission, or SEC, under the Securities Exchange Act of 1934, or the Exchange Act. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including Regeneron, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at http://www.sec.gov.

We also make available free of charge on or through our Internet website (http://www.regn.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. ***Risk Factors***

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3153

Samsung Bioepis Exhibit 1017, pg. 3153

our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through December 31, 2007, we had a cumulative loss of $793.2 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt that is scheduled to mature in 2008.

We have $200.0 million of convertible debt that, unless converted to shares of our Common Stock, will mature in October 2008. Our debt obligations could require us to use a significant portion of our cash to pay principal and interest on our debt.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are studying our lead product candidates, aflibercept, VEGF Trap-Eye, and ARCALYST™, in a wide variety of indications. We are studying aflibercept in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and ARCALYST™ in a variety of systemic inflammatory disorders.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3154

Samsung Bioepis Exhibit 1017, pg. 3154

Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are being, or are planned to be, studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of ARCALYST™ in different diseases after a Phase 2 trial using lower doses of ARCALYST™ in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

The data from the Phase 3 clinical program for ARCALYST™ in CAPS (Cryopyrin-Associated Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of ARCALYST™.

We submitted a completed BLA to the FDA for ARCALYST™ in CAPS in the second quarter of 2007. However, the efficacy and safety data from the Phase 3 clinical program included in the BLA may be inadequate to support approval for commercialization of ARCALYST™. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance.

Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for ARCALYST™, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize ARCALYST™ profitably.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST™ in those countries.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3155

Samsung Bioepis Exhibit 1017, pg. 3155

Serious complications or side effects have occurred, and may continue to occur, in clinical trials of some of our product candidates which could lead to delay or discontinuation of development and severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These serious and potentially life-threatening risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, intestinal perforation, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These include side effects that we have not yet seen in our trials such as heart attack and stroke. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

It is possible that safety or tolerability concerns may arise as we continue to test ARCALYST™ in patients with inflammatory diseases and disorders. Like cytokine antagonists such as Kineret® (Amgen), Enbrel® (Immunex), and Remicade® (Centocor), ARCALYST™ affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST™ may interfere with the body's ability to fight infections. Treatment with Kineret® (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious infections have been reported in patients taking ARCALYST™. One subject with adult Still's diseases in a study of ARCALYST™ developed an infection in his elbow with mycobacterium intracellulare. The patient was on chronic glucocorticoid treatment for Still's disease. The infection occurred after an intraarticular glucocorticoid injection into the elbow and subsequent local exposure to a suspected source of mycobacteria. One patient with polymayalgia rheumatica in another study developed bronchitis/sinusitis, which resulted in hospitalization. One patient in an open-label study of ARCALYST™ in CAPS developed sinusitis and streptococcus pneumoniae meningitis and subsequently died. In addition, patients given infusions of ARCALYST™ have developed hypersensitivity reactions or infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of ARCALYST™.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Of the clinical study subjects who

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3156

Samsung Bioepis Exhibit 1017, pg. 3156

received ARCALYST™ for rheumatoid arthritis and other indications, fewer than 5% of patients developed antibodies and no side effects related to antibodies were observed. Using a very sensitive test, approximately 40% of the patients in the CAPS pivotal study tested positive at least once for low levels of antibodies to ARCALYST™. Again, no side effects related to antibodies were observed and there were no observed effects on drug efficacy or drug levels. However, it is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, ARCALYST™, and REGN88, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune* technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that aflibercept or the VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or the VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or the VEGF Trap-Eye, which

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3157

Samsung Bioepis Exhibit 1017, pg. 3157

represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell aflibercept or the VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

In December 2003, we entered into a non-exclusive license agreement with Cellectis Inc. that granted us certain rights in a family of patents relating to homologous recombination. Cellectis now claims that agreements we entered into relating to our *VelocImmune* mice with AstraZeneca, Astellas, and sanofi-aventis are outside of the scope of our license from Cellectis. We disagree with Cellectis' position and are in discussions with Cellectis regarding this matter. If we are not able to resolve this dispute, Cellectis may commence a lawsuit against us and our *VelocImmune* licensees alleging infringement of Cellectis' patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3158

Samsung Bioepis Exhibit 1017, pg. 3158

application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated rules and listing standards covering a variety of subjects. Compliance with these rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2007, which report is included in this Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3159

Samsung Bioepis Exhibit 1017, pg. 3159

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $475.0 million between 2008 and 2012 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. Sanofi-aventis may terminate the collaboration for our material breach or, in the case of the discovery agreement, if certain minimal criteria for the discovery program are not achieved by December 31, 2010. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business, operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development and commercialization of aflibercept.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3160

Samsung Bioepis Exhibit 1017, pg. 3160

If our collaboration with Bayer HealthCare for the VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, operations and financial condition, and our ability to develop and commercialize the VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of the VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional finding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of the VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the manufacture, development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3161

Samsung Bioepis Exhibit 1017, pg. 3161

be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with commercial capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3162

Samsung Bioepis Exhibit 1017, pg. 3162

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin® (Genentech), and their extensive, ongoing clinical development plan for Avastin® (Genentech) in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute recently has received funding for a Phase 3 trial to compare Lucentis® (Genentech) to Avastin® (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis® (Genentech) and the potential off-label use of Avastin® (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis® (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin® (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST™. This is one of the reasons we discontinued the development of ARCALYST™ in adult rheumatoid arthritis. In addition, even if ARCALYST™ is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST™, such as requiring fewer injections.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3163

Samsung Bioepis Exhibit 1017, pg. 3163

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has commenced advanced clinical testing of its IL-1 antibody in Muckle-Wells Syndrome, which is part of the group of rare genetic diseases called CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST™. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYST™. For example, we may find it difficult to enroll patients in clinical trials for ARCALYST™ if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing ARCALYST™ for the treatment of a group of rare diseases associated with mutations in the NLRP3 gene. These rare genetic disorders affect a small group of people, estimated to be in the hundreds. There may be too few patients with these genetic disorders to profitably commercialize ARCALYST™ in this indication.

We are developing REGN88 for the treatment of rheumatoid arthritis. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott), and other marketed therapies makes it more difficult to successfully develop and commercialize REGN88. REGN88 is a human monoclonal antibody targeting the interleukin-6 receptor. Roche is developing an antibody against the interleukin-6 (IL-6) receptor. Roche's antibody has completed Phase 3 clinical trials and is the subject of a filed Biologics License Application with the FDA. Roche's IL-6 receptor antibody, other clinical candidates in development, and drugs now or in the future on the market to treat rheumatoid arthritis could offer competitive advantages over REGN88. This could delay or impair our ability to successfully develop and commercialize REGN88.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We are seeking approval to market ARCALYST™ for the treatment of a group of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST™. Physicians may not prescribe ARCALYST™ and CAPS patients may not be able to afford ARCALYST™ if third party payers do not agree to reimburse the cost of ARCALYST™ therapy and this would adversely affect our ability to commercialize ARCALYST™ profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including ARCALYST™, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3164

Samsung Bioepis Exhibit 1017, pg. 3164

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of December 31, 2007, our seven largest shareholders beneficially owned 54.0% of our outstanding shares of Common

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3165

Samsung Bioepis Exhibit 1017, pg. 3165

Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of December 31, 2007. As of December 31, 2007, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 19.3% of the shares of Common Stock then outstanding. Under our investor agreement with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2012 except under limited circumstances and subject to earlier termination rights of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2007, holders of Class A Stock held 22.8% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of December 31, 2007:

- our current executive officers and directors beneficially owned 12.6% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2007, and 27.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2007; and
- our seven largest shareholders beneficially owned 54.0% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of December 31, 2007. In addition, these seven shareholders held 58.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of December 31, 2007.

Pursuant to an investor agreement, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3166

Samsung Bioepis Exhibit 1017, pg. 3166

other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of the Company's Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our chief executive officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. We currently lease approximately 232,000 square feet of laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, we entered into a new operating lease agreement for approximately 221,000 square feet of laboratory and office space at the Company's current Tarrytown location. The new lease includes approximately 27,000 square feet that we currently occupy (the "retained facilities") and approximately 194,000 square feet to be located in new facilities that are under construction and expected to be completed in mid-2009. In October 2007, we amended the December 2006 operating lease agreement to increase the amount of new space we will lease from approximately 194,000 square feet to approximately 230,000 square feet, for an amended total under the new lease of approximately 257,000 square feet. The term of the lease is expected to commence in mid-2008 and will expire approximately 16 years later. Under the new lease we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3167

Samsung Bioepis Exhibit 1017, pg. 3167

for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In November 2007 we entered into a new operating sublease for approximately 10,000 square feet of office space in Tarrytown, New York. The lease expires in September 2009 and we have the option to extend the term for two additional terms of three months each.

We own a facility in Rensselaer, New York, consisting of two buildings totaling approximately 123,500 square feet of research, manufacturing, office, and warehouse space. In June 2007, we exercised a purchase option on a 272,000 square foot building in Rensselaer, New York. Prior to the purchase, which was completed in October 2007, the Company leased approximately 75,000 square feet of manufacturing, office, and warehouse space in that building.

The following table summarizes the information regarding our current property leases:

Location	Square Footage	Expiration	Current Monthly Base Rental Charges (1)	Renewal Option Available
Tarrytown (2)	205,000	June, 2009 (3)	$ 311,000	None
Tarrytown (2)	230,000	June, 2024 (3)		Three 5-year terms
Tarrytown	27,000	June, 2024 (3)	$ 54,000	Three 5-year terms
Tarrytown (4)	10,000	September, 2009	$ 22,000	Two 3-month terms

(1) Excludes additional rental charges for utilities, taxes, and operating expenses, as defined.

(2) Upon completion of the new facilities, as described above, we will release the 205,000 square feet of space in our current facility and take over 230,000 square feet in the newly constructed buildings.

(3) Estimated based upon expected completion of our new facilities, as described above.

(4) Relates to sublease in Tarrytown, New York as described above.

We believe that our existing owned and leased facilities are adequate for ongoing, research, development, manufacturing, and administrative activities.

In the future, we may lease, operate, or purchase additional facilities in which to conduct expanded research and development activities and manufacturing and commercial operations.

Item 3. ***Legal Proceedings***

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of our security holders during the last quarter of the fiscal year ended December 31, 2007.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3168

Samsung Bioepis Exhibit 1017, pg. 3168

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities***

Our Common Stock is quoted on The NASDAQ Stock Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The NASDAQ Stock Market:

	High	Low
2006		
First Quarter	$ 18.00	$ 14.35
Second Quarter	16.69	10.97
Third Quarter	17.00	10.88
Fourth Quarter	24.85	15.27
2007		
First Quarter	$ 22.84	$ 17.87
Second Quarter	28.74	17.55
Third Quarter	21.78	13.55
Fourth Quarter	24.90	16.77

As of February 15, 2008, there were 515 shareholders of record of our Common Stock and 42 shareholders of record of our Class A Stock.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

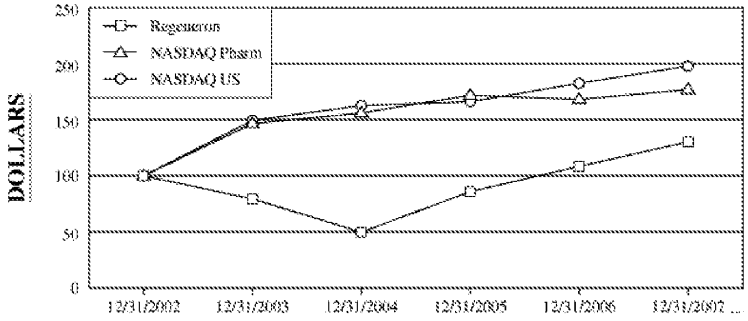
The information under the heading "Equity Compensation Plan Information" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Report on Form 10-K.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3169

Samsung Bioepis Exhibit 1017, pg. 3169

STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) The Nasdaq Pharmaceuticals Stocks Index and (ii) The Nasdaq Stock Market (U.S.) Index for the period from December 31, 2002 through December 31, 2007. The comparison assumes that $100 was invested on December 31, 2002 in our Common Stock and in each of the foregoing indices. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices. The historical stock price performance of our Common Stock shown in the graph below is not necessarily indicative of future stock price performance.



	12/31/2002	12/31/2003	12/31/2004	12/31/2005	12/31/2006	12/31/2007
Regeneron	$100.00	$ 79.47	$ 49.76	$ 85.90	$108.43	$130.47
Nasdaq Pharm	100.00	146.59	156.13	171.93	168.29	176.97
Nasdaq US	100.00	149.52	162.72	166.18	182.57	197.98

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3170

Samsung Bioepis Exhibit 1017, pg. 3170

Item 6. ***Selected Financial Data***

The selected financial data set forth below for the years ended December 31, 2007, 2006, and 2005 and at December 31, 2007 and 2006 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2004 and 2003 and at December 31, 2005, 2004, and 2003 are derived from our audited financial statements not included in this report.

	Year Ended December 31,				
	2007	2006	2005	2004	2003
	(In thousands, except per share data)				
Statement of Operations Data					
Revenues					
Contract research and development	$ 96,603	$ 51,136	$ 52,447	$ 113,157	$ 47,366
Research progress payments				42,770	
Contract manufacturing		12,311	13,746	18,090	10,131
Technology licensing	28,421				
	125,024	63,447	66,193	174,017	57,497
Expenses					
Research and development	201,613	137,064	155,581	136,095	136,024
Contract manufacturing		8,146	9,557	15,214	6,676
General and administrative	37,865	25,892	25,476	17,062	14,785
	239,478	171,102	190,614	168,371	157,485
Income (loss) from operations	(114,454)	(107,655)	(124,421)	5,646	(99,988)
Other income (expense)					
Other contract income			30,640	42,750	
Investment income	20,897	16,548	10,381	5,478	4,462
Interest expense	(12,043)	(12,043)	(12,046)	(12,175)	(11,932)
	8,854	4,505	28,975	36,053	(7,470)
Net income (loss) before cumulative effect of a change in accounting principle	(105,600)	(103,150)	(95,446)	41,699	(107,458)
Cumulative effect of adopting Statement of Accounting Standards No. 123R ("SFAS 123R")		813			
Net income (loss)	$ (105,600)	$ (102,337)	$ (95,446)	$ 41,699	$ (107,458)
Net income (loss) per share, basic:					
Net income (loss) before cumulative effect of a change in accounting principle	$ (1.59)	$ (1.78)	$ (1.71)	$ 0.75	$ (2.13)
Cumulative effect of adopting SFAS 123R		0.01			
Net income (loss)	$ (1.59)	$ (1.77)	$ (1.71)	$ 0.75	$ (2.13)
Net income (loss) per share, diluted	$ (1.59)	$ (1.77)	$ (1.71)	$ 0.74	$ (2.13)

	At December 31,				
	2007	2006	2005	2004	2003
			(In thousands)		
Balance Sheet Data					
Cash, cash equivalents, restricted cash, marketable securities, and restricted marketable securities (current and non-current)	$ 846,279	$ 522,859	$ 316,654	$ 348,912	$ 366,566
Total assets	936,258	585,090	423,501	473,108	479,555
Notes payable — current portion	200,000				
Notes payable — long-term portion		200,000	200,000	200,000	200,000
Stockholders' equity	460,267	216,624	114,002	182,543	137,643

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3171

Samsung Bioepis Exhibit 1017, pg. 3171

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

Overview

We are a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We currently have four clinical development programs, including three late-stage clinical programs: ARCALYST™ (rilonacept; also known as IL-1 Trap) in various inflammatory indications, aflibercept (VEGF Trap) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. Aflibercept is being developed in oncology in collaboration with sanofi-aventis. The VEGF Trap-Eye is being developed in collaboration with Bayer HealthCare LLC. Our fourth clinical development program is REGN88, an antibody to the Interleukin-6 receptor (IL-6R) that entered clinical development in patients with rheumatoid arthritis in the fourth quarter of 2007. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and we may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through December 31, 2007, we had a cumulative loss of $793.2 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and ARCALYST™; advance new product candidates into clinical development from our existing research programs utilizing our technology for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

As a company that does not expect to be profitable over the next several years, management of cash flow is extremely important. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. We are reimbursed for some of these research and development activities by our collaborators. Our principal sources of cash to-date have been from sales of common equity and convertible debt and from funding from our collaborators in the form of up-front payments, research progress payments, and payments for our research and development activities.

In 2007, our research and development expenses totaled $201.6 million. In 2008, we expect these expenses to increase substantially as we (i) expand our research and preclinical and clinical development activities in connection with our new antibody collaboration with sanofi-aventis, (ii) expand our Phase 3 VEGF Trap-Eye clinical program and our ARCALYST™ and aflibercept clinical programs, and (iii) increase our research and development headcount. Due to our new antibody collaboration with sanofi-aventis, we expect a greater proportion of our research and development expenses to be funded by our collaborators in 2008 than in 2007.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2007 was 627 compared with 573 in 2006 and 696 in 2005. In 2007 our average headcount increased primarily to support our expanded development programs for the VEGF Trap-Eye and ARCALYST™ and our plans to move our first antibody candidate into clinical trials. In 2006, our average headcount decreased primarily as a result of reductions

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3172

Samsung Bioepis Exhibit 1017, pg. 3172

made in the fourth quarter of 2005 and mid-year in 2006. These workforce reductions were associated with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in October 2006. In 2008, we expect our average headcount to increase to approximately 825-875 primarily to support the expansion of our research and development activities as described above, especially in connection with our new antibody collaboration with sanofi-aventis.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2007 and plans for 2008 are as follows:

Product Candidate	2007 Events	2008 Events/Plans
ARCALYST™ (rilonacept; also known as IL-1 Trap)	• Completed the 24-week open-label safety extension phase of the Phase 3 trial in CAPS • FDA accepted BLA submission for CAPS • Granted Orphan Drug designation in CAPS in European Union • Reported positive results in exploratory proof-of-concept study in patients with chronic active gout • Initiated Phase 2 trial evaluating safety and efficacy of ARCALYST™ in preventing gout-induced flares in patients initiating allopurinol therapy	• Receive FDA review decision on BLA submission for CAPS (expected at the end of February 2008) • If marketing approval is obtained, launch ARCALYST™ commercially in CAPS • Evaluate ARCALYST™ in certain other disease indications in which IL-1 may play an important role
Aflibercept (VEGF Trap — Oncology)	• Sanofi-aventis initiated four Phase 3 trials of aflibercept in combination with standard chemotherapy regimens • NCI/CTEP initiated 10 studies of aflibercept • Reported interim results from Phase 2 single-agent trials in advanced ovarian cancer and in non-small cell lung adenocarcinoma • Initiated Japanese Phase 1 trial of aflibercept in combination with another investigational agent in patients with solid malignancies	• Sanofi-aventis to initiate a fifth Phase 3 study of aflibercept in combination with standard chemotherapy regimen • Report final data from Phase 2 single-agent trials in advanced ovarian cancer and in non-small cell lung adenocarcinoma • Complete enrollment of Phase 2 single-agent study in symptomatic malignant ascites (SMA) • Report interim data from the SMA Phase 2 trial • NCI/CTEP to begin to report data from trials • NCI/CTEP to initiate additional exploratory safety and efficacy studies
VEGF Trap-Eye (intravitreal injection)	• Initiated first Phase 3 trial in wet AMD in patients in the U.S. and Canada • Reported positive primary endpoint results and preliminary extended treatment results of Phase 2 trial in wet AMD • Reported positive results in Phase 1 trial in DME	• Initiate second Phase 3 trial in wet AMD in the European Union and certain other countries around the world • Explore additional eye disease indications

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3173

Samsung Bioepis Exhibit 1017, pg. 3173

Product Candidate	2007 Events	2008 Events/Plans
Antibodies	• Entered global, strategic collaboration agreement with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies • Initiated Phase 1 trial for REGN88 in rheumatoid arthritis	• Initiate Phase 1 trial for the Dll4 antibody in oncology • Report data for Phase 1 trial of REGN88 in rheumatoid arthritis • Advance a third antibody candidate into clinical development

Collaborations

Our current collaboration agreements with sanofi-aventis and Bayer HealthCare, and our expired agreement with The Procter & Gamble Company, are summarized below.

The sanofi-aventis Group

Aflibercept

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. Sanofi-aventis made a non-refundable, up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for $45.0 million.

In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In connection with this amendment, sanofi-aventis made a $25.0 million non-refundable payment to us.

In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a $25.0 million non-refundable, up-front payment to us, which was received in January 2006. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept. We may also receive up to $400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to $360.0 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union. Another $40.0 million of milestone payments relate to receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

We have agreed to manufacture clinical supplies of aflibercept at our plant in Rensselaer, New York. Sanofi-aventis has agreed to be responsible for providing commercial scale manufacturing capacity for aflibercept.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. Since inception of the collaboration through December 31, 2007, we and sanofi-aventis have incurred $306.8 million in agreed upon development expenses related to the aflibercept program. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to $7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3174

Samsung Bioepis Exhibit 1017, pg. 3174

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of aflibercept development expenses will terminate and we will retain all rights to aflibercept.

Antibodies

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The first therapeutic antibody to enter clinical development under the collaboration, REGN88, is an antibody to the Interleukin-6 receptor (IL-6R), which has started clinical trials in rheumatoid arthritis. The second is expected to be an antibody to Delta-like ligand-4 (Dll4), which is currently slated to enter clinical development in mid-2008.

The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis will fund up to $475.0 million of our research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against such targets through December 31, 2012, subject to specified funding limits of $75.0 million for the period from the collaboration's inception through December 31, 2008, and $100.0 million annually in each of the next four years. The discovery agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate (called Shared Phase 3 Trial Costs) will be shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of $0.7 million as of December 31, 2007) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the license agreement, we will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party and, in the case of the discovery agreement, a

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3175

Samsung Bioepis Exhibit 1017, pg. 3175

termination right for sanofi-aventis under certain circumstances, including if certain minimal criteria for the discovery program are not achieved. Prior to December 31, 2012, sanofi-aventis has the right to terminate the discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

In December 2007, we sold sanofi-aventis 12 million newly issued, unregistered shares of Common Stock at an aggregate cash price of $312.0 million, or $26.00 per share of Common Stock. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with us. Under the investor agreement, sanofi-aventis has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the license and collaboration agreement and the existing collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept, sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Sanofi-aventis has also agreed not to dispose of any shares of Common Stock that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2012, subject to certain limited exceptions. Following December 20, 2012, sanofi-aventis will be permitted to sell shares of Common Stock (i) in a registered underwritten public offering undertaken pursuant to the demand registration rights granted to sanofi- aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or more of the outstanding shares of Common Stock and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by our Board of Directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of our voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by our Board of Directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Shares, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

Bayer HealthCare LLC

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, the VEGF Trap-Eye. Under the terms of the agreement, Bayer HealthCare made a non-refundable, up-front payment to us of $75.0 million. In August 2007, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in wet AMD, and are eligible to receive up to $90.0 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. We are also eligible to receive up to an additional $135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200.0 million.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of $25.4 million at December 31, 2007) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. Within the United States, we are responsible for any future commercialization of the VEGF Trap-Eye and retain exclusive rights to any future profits from commercialization.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3176

Samsung Bioepis Exhibit 1017, pg. 3176

Agreed upon development expenses incurred by both companies in 2007 under a global development plan were shared as follows: The first $50.0 million was shared equally and we were solely responsible for up to the next $40.0 million. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

In 2008, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first $70.0 million will be shared equally, we are solely responsible for up to the next $30.0 million, and over $100.0 million will be shared equally. In 2009 and thereafter, all development expenses will be shared equally. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

Bayer HealthCare has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue for financial statement purposes. In the fourth quarter of 2007, we and Bayer HealthCare approved a global development plan for the VEGF Trap-Eye in wet AMD. The plan includes estimated development steps, timelines, and costs, as well as the projected responsibilities of each of the companies. In addition, in the fourth quarter of 2007, we and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for the VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, we determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's VEGF Trap-Eye development expenses, and the financial statement classifications and periods in which past and future payments from Bayer HealthCare (including the $75.0 million up-front payment and development and regulatory milestone payments) and cost-sharing of VEGF Trap-Eye development expenses will be recognized in our Statement of Operations.

The Procter & Gamble Company

In May 1997, we entered into a long-term collaboration with Procter & Gamble to discover, develop, and commercialize pharmaceutical products, and Procter & Gamble agreed to provide funding in support of our research efforts related to the collaboration. In accordance with the companies' collaboration agreement, Procter & Gamble was obligated to fund our research on therapeutic areas that were of particular interest to Procter & Gamble through December 2005, with no further research obligations by either party thereafter. Under the collaboration agreement, research support from Procter & Gamble was $2.5 million per quarter, plus annual adjustments for inflation, through December 2005.

In June 2005, we and Procter & Gamble amended our collaboration agreement. Under the terms of the modified agreement, the two companies agreed that the research activities being pursued under the collaboration agreement were completed on June 30, 2005, six months prior to the December 31, 2005 expiration date in the collaboration agreement. Procter & Gamble agreed to make a one-time $5.6 million payment to Regeneron, which was received in July 2005, and to fund our research under the agreement through the second quarter of 2005. We agreed to pay Procter & Gamble approximately $1.0 million to acquire certain capital equipment owned by Procter & Gamble and located at our facilities. We and Procter & Gamble divided rights to research programs and preclinical product candidates that were developed during the research term of the collaboration. Neither party has the right to participate in the development or commercialization of the other party's product candidates. We are entitled to receive royalties based on any future product sales of a Procter & Gamble preclinical candidate arising from the collaboration, and Procter & Gamble is entitled to receive a small royalty on any sales of a single Regeneron candidate that is not currently being developed. Neither party is entitled to receive either royalties or other payments based on any other products arising from the collaboration.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3177

Samsung Bioepis Exhibit 1017, pg. 3177

Other Agreements

AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million non-refundable, up-front payment to us. AstraZeneca is required to make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million non-refundable, up-front payment to us. Astellas is required to make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

National Institutes of Health

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We use our *VelociGene®* technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our *VelociGene* technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse embryonic stem cells (ES cells) which can be used to produce knockout mice. These materials will be made widely available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, we are entitled to receive a minimum of $17.9 million over a five-year period. We will receive another $1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. (SFAS) 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date. Prior to the adoption of the fair value method, we accounted for stock-based compensation to employees under the intrinsic value method of accounting set forth in Accounting Principles Board Opinion No. (APB) 25, *Accounting for Stock Issued to Employees*, and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period operating results were not restated.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3178

Samsung Bioepis Exhibit 1017, pg. 3178

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005, and prior to our adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that were not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by $0.8 million and is included in our operating results for the year ended December 31, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on our loss from operations, net loss, and net loss per share for the year ended December 31, 2006 was not significant, and there was no impact to our cash flows for the year ended December 31, 2006.

Non-cash stock-based employee compensation expense related to stock option awards (Stock Option Expense) recognized in operating expenses totaled $28.0 million, $18.4 million, and $19.9 million for the years ended December 31, 2007, 2006, and 2005, respectively. In addition, for the year ended December 31, 2005, $0.1 million of Stock Option Expense was capitalized into inventory. As of December 31, 2007, there was $60.6 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.8 years. In addition, there are 723,092 options which are unvested as of December 31, 2007 and would become vested upon our products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals $2.7 million and will begin to be recognized only if, and when, these options' performance condition is considered to be probable of attainment.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average values of the assumptions we used in computing the fair value of option grants during 2007, 2006, and 2005:

	2007	2006	2005
Expected volatility	53%	67%	71%
Expected lives from grant date	5.6 years	6.5 years	5.9 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	3.60%	4.51%	4.16%

Changes in any of these assumptions may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3179

Samsung Bioepis Exhibit 1017, pg. 3179

Results of Operations

Years Ended December 31, 2007 and 2006

Net Loss:

Regeneron reported a net loss of $105.6 million, or $1.59 per share (basic and diluted), for the year ended December 31, 2007, compared to a net loss of $102.3 million, or $1.77 per share (basic and diluted) for 2006.

Revenues:

Revenues for the years ended December 31, 2007 and 2006 consist of the following:

	2007	2006
	(In millions)	
Contract research & development revenue		
Sanofi-aventis	$ 51.7	$ 47.8
Bayer HealthCare	35.9	
Other	9.0	3.3
Total contract research & development revenue	96.6	51.1
Contract manufacturing revenue		12.3
Technology licensing revenue	28.4	
Total revenue	$ 125.0	$ 63.4

We recognize revenue from sanofi-aventis, in connection with our aflibercept and antibody collaborations, in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and FASB Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21) (see "Critical Accounting Policies and Significant Judgments and Estimates"). We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable, up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration. Non-refundable, up-front payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance periods based on the specific terms of the collaboration agreements, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

Sanofi-aventis Contract Research & Development Revenue	December 31, 2007	2006
	(In millions)	
Aflibercept:		
Regeneron expense reimbursement	$ 38.3	$ 36.4
Recognition of deferred revenue related to up-front payments	8.8	11.4
Total aflibercept	47.1	47.8
Antibody:		
Regeneron expense reimbursement	3.7	
Recognition of deferred revenue related to up-front payments	0.9	
Total antibody	4.6	
Total sanofi-aventis contract research & development revenue	$ 51.7	$ 47.8

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses increased in 2007 compared to 2006, primarily due to higher preclinical and clinical development costs. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments decreased in 2007 from 2006 due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of December 31, 2007, $61.2 million

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3180

Samsung Bioepis Exhibit 1017, pg. 3180

of the original $105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2007, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of $3.0 million under the collaboration's discovery agreement and $0.7 million of REGN88 development costs under the license agreement. Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' $85.0 million up-front payment. As of December 31, 2007, $84.1 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. The $75.0 million up-front licensing payment and the $20.0 million milestone payment (which was received in August 2007 and not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue over the related estimated performance period in accordance with SAB 104 and EITF 00-21. In periods when we recognize VEGF Trap-Eye development expenses that we incur under the collaboration, we also recognize, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, when we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, we recognized, as a cumulative catch-up, contract research and development revenue of $35.9 million, consisting of (i) $15.9 million related to the $75.0 million up-front licensing payment and the $20.0 million milestone payment, and (ii) $20.0 million related to the portion of our 2007 VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. As of December 31, 2007, $79.1 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes $5.5 million and $0.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue in 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in 2006 was $1.2 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the $20.0 million non-refundable, up-front payment, which we received in February 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the $20.0 million non-refundable, up-front payment, which we received in April 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. For the year ended December 31, 2007, we recognized $28.4 million of technology licensing revenue related to these agreements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3181

Samsung Bioepis Exhibit 1017, pg. 3181

Expenses:

Total operating expenses increased to $239.5 million in 2007 from $171.1 million in 2006. Our average employee headcount in 2007 increased to 627 from 573 in 2006, primarily to support our expanded development programs for the VEGF Trap-Eye and ARCALYST™ and our activities to move our first antibody candidate (REGN88) into clinical trials. Operating expenses in 2007 and 2006 include a total of $28.0 million and $18.4 million of Stock Option Expense, respectively, as detailed below:

	For the Year Ended December 31, 2007		
Expenses	**Expenses Before Inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
		(In millions)	
Research and development	$ 185.5	$ 16.1	$ 201.6
General and administrative	26.0	11.9	37.9
Total operating expenses	$ 211.5	$ 28.0	$ 239.5

	For the Year Ended December 31, 2006		
Expenses	**Expenses Before Inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
		(In millions)	
Research and development	$ 126.9	$ 10.2	$ 137.1
Contract manufacturing	7.8	0.3	8.1
General and administrative	18.0	7.9	25.9
Total operating expenses	$ 152.7	$ 18.4	$ 171.1

The increase in total Stock Option Expense in 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

Research and Development Expenses:

Research and development expenses increased to $201.6 million for the year ended December 31, 2007 from $137.1 million for 2006. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2007 and 2006:

	Year Ended December 31,		
Research and Development Expenses	**2007**	**2006**	**Increase (Decrease)**
		(In millions)	
Payroll and benefits (1)	$ 60.6	$ 44.8	$ 15.8
Clinical trial expenses	37.6	14.9	22.7
Clinical manufacturing costs (2)	47.0	39.2	7.8
Research and preclinical development costs	23.2	17.5	5.7
Occupancy and other operating costs	22.6	20.7	1.9
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	10.6		10.6
Total research and development	$ 201.6	$ 137.1	$ 64.5

(1) Includes $13.1 million and $8.4 million of Stock Option Expense for the years ended December 31, 2007 and 2006, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3182

Samsung Bioepis Exhibit 1017, pg. 3182

depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $3.0 million and $1.8 million of Stock Option Expense for the years ended December 31, 2007 and 2006, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of their VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, when we commenced recognizing cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, we recognized as additional research and development expense a cumulative catch-up of $10.6 million of VEGF Trap-Eye development expenses that we were obligated to reimburse to Bayer HealthCare.

Payroll and benefits increased primarily due to the increase in employee headcount, as described above, annual compensation increases effective in 2007, and higher Stock Option Expense, as described above. Clinical trial expenses increased due primarily to higher costs related to our Phase 3 study of the VEGF Trap-Eye in wet AMD, which we initiated in the third quarter of 2007, and our ongoing Phase 1 and 2 studies of the VEGF Trap-Eye in wet AMD. Clinical manufacturing costs increased due primarily to higher costs related to manufacturing ARCALYST™ and preclinical and clinical supplies of REGN88, which were partly offset by lower costs related to manufacturing aflibercept and the VEGF Trap-Eye. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs, including REGN88, and utilization of our proprietary technology platforms. Occupancy and other operating costs primarily increased in connection with higher Company headcount and to support our expanded research and development activities.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Stock Option Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	Year Ended December 31,		
Project Costs	**2007**	**2006**	**Increase (Decrease)**
		(In millions)	
ARCALYST™	$ 38.1	$ 29.6	$ 8.5
Aflibercept	33.7	30.7	3.0
VEGF Trap-Eye	53.7	21.9	31.8
REGN88	13.6		13.6
Other research programs & unallocated costs	62.5	54.9	7.6
Total research and development expenses	$ 201.6	$ 137.1	$ 64.5

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3183

Samsung Bioepis Exhibit 1017, pg. 3183

which we will be developing a product. For example, we, and our collaborators, where applicable, continue to explore further development of ARCALYST™, aflibercept, and the VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows. In the second quarter of 2007, we submitted a BLA for ARCALYST™ for the treatment of CAPS, a group of rare genetic disorders. We cannot predict whether or when the commercialization of ARCALYST™ in CAPS will result in a material net cash inflow to us.

Contract Manufacturing Expenses:

We had no contract manufacturing expenses in 2007 compared to $8.1 million in 2006, due to the expiration of our manufacturing agreement with Merck in October 2006.

General and Administrative Expenses:

General and administrative expenses increased to $37.9 million in 2007 from $25.9 million in the same period of 2006 primarily due to (i) higher Stock Option Expense, as described above, (ii) higher compensation expense principally due to annual increases effective in 2007 and higher administrative headcount to support our expanded research and development activities, (iii) recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) market research and related expenses incurred in 2007 in connection with our ARCALYST™ and VEGF Trap-Eye programs.

Other Income and Expense:

Investment income increased to $20.9 million in 2007 from $16.5 million in 2006, resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). This increase was partly offset by a $5.9 million charge in 2007 related to marketable securities which we considered to be other than temporarily impaired in value. In the second half of 2007, deterioration in the credit quality of marketable securities from two issuers has subjected us to the risk of being unable to recover their full principal value, which totals $14.0 million. Interest expense was $12.0 million in 2007 and 2006. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

Years Ended December 31, 2006 and 2005

Net Loss:

Regeneron reported a net loss of $102.3 million, or $1.77 per share (basic and diluted), for the year ended December 31, 2006, compared to a net loss of $95.4 million, or $1.71 per (basic and diluted) for 2005.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3184

Samsung Bioepis Exhibit 1017, pg. 3184

Revenues:

Revenues for the years ended December 31, 2006 and 2005 consist of the following:

	2006	2005
	(In millions)	
Contract research & development revenue		
Sanofi-aventis	$ 47.8	$ 43.4
Procter & Gamble		6.0
Other	3.3	3.1
Total contract research & development revenue	51.1	52.5
Contract manufacturing revenue	12.3	13.7
Total revenue	$ 63.4	$ 66.2

We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of $105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

	December 31,	
Sanofi-aventis Contract Research & Development Revenue	2006	2005
	(In millions)	
Regeneron expense reimbursement	$ 36.4	$ 33.9
Recognition of deferred revenue related to up-front payments	11.4	9.5
Total	$ 47.8	$ 43.4

Sanofi-aventis' reimbursement of Regeneron aflibercept expenses increased in 2006 compared to 2005, primarily due to higher costs related to our manufacture of aflibercept clinical supplies during the first half of 2006. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in 2006 from the same period in 2005, due to our receipt in January 2006 of a $25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' aflibercept collaboration to include Japan. As of December 31, 2006, $70.0 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract research and development revenue earned from Procter & Gamble decreased in 2006 compared to 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005, as described above under "Collaborations — The Procter & Gamble Company." Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

In October 2006 we entered into our VEGF Trap-Eye collaboration with Bayer HealthCare. In the fourth quarter of 2007, we determined the appropriate accounting policy for payments from Bayer HealthCare and, in 2007, commenced recognizing previously deferred payments in our Statement of Operations through a cumulative catch-up, as described above. Accordingly, there was no contract research and development revenue earned from Bayer HealthCare in 2006. As of December 31, 2006, the $75.0 million up-front payment received from Bayer HealthCare in October 2006 was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes $0.5 million recognized in connection with our NIH Grant, as described above.

Contract manufacturing revenue relates to our long-term agreement with Merck, which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer facility. Contract manufacturing revenue decreased in 2006 compared to 2005 due to a decrease in product shipments to Merck in 2006. Revenue and the related

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3185

Samsung Bioepis Exhibit 1017, pg. 3185

manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in 2006 and 2005 were $1.2 million and $1.4 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck and there was no Merck deferred revenue as of the end of 2006.

Expenses:

Total operating expenses decreased to $171.1 million in 2006 from $190.6 million in 2005 due, in part, to our lower headcount, as described above. (Also see "Severance Costs" below.)

Operating expenses in 2006 and 2005 include a total of $18.4 million and $19.9 million of Stock Option Expense, respectively, as detailed below:

	For the Year Ended December 31, 2006		
Expenses	Expenses Before Inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 126.9	$ 10.2	$ 137.1
Contract manufacturing	7.8	0.3	8.1
General and administrative	18.0	7.9	25.9
Total operating expenses	$ 152.7	$ 18.4	$ 171.1

	For the Year Ended December 31, 2005		
Expenses	Expenses Before Inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 143.7	$ 11.9	$ 155.6
Contract manufacturing	9.2	0.4	9.6
General and administrative	17.8	7.6	25.4
Total operating expenses	$ 170.7	$ 19.9	$ 190.6

Research and Development Expenses:

Research and development expenses decreased to $137.1 million for the year ended December 31, 2006 from $155.6 million for 2005. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2006 and 2005:

	Year Ended December 31,		
Research and Development Expenses	2006	2005	Increase (Decrease)
Payroll and benefits (1)	$ 44.8	$ 53.6	$ (8.8)
Clinical trial expenses	14.9	18.2	(3.3)
Clinical manufacturing costs (2)	39.2	41.6	(2.4)
Research and preclinical development costs	17.5	19.2	(1.7)
Occupancy and other operating costs	20.7	23.0	(2.3)
Total research and development	$ 137.1	$ 155.6	$ (18.5)

(1) Includes $8.4 million and $10.5 million of Stock Option Expense for the years ended December 31, 2006 and 2005, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $1.8 million and $1.4 million of Stock Option Expense for the years ended December 31, 2006 and 2005, respectively.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3186

Samsung Bioepis Exhibit 1017, pg. 3186

Payroll and benefits decreased principally due to our lower headcount in 2006. In addition, payroll and benefits in 2006 and 2005 included $0.4 million and $2.2 million, respectively, of severance costs associated with our workforce reduction plan that we initiated in October 2005. Clinical trial expenses decreased primarily due to lower ARCALYST™ costs in 2006 as we discontinued clinical development of ARCALYST™ in adult rheumatoid arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased because of lower costs in 2006 related to manufacturing ARCALYST™ clinical supplies, which were partially offset by higher costs related to manufacturing aflibercept clinical supplies. Research and preclinical development costs decreased principally because of lower costs for general research supplies in 2006 as we narrowed the focus of our research and development efforts due, in part, to the expiration of our collaboration with Procter & Gamble in June 2005, as described above. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount and lower costs for utilities associated with our leased research facilities in Tarrytown, New York.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, non-cash stock-based employee compensation expense related to stock option awards, and manufacturing and other costs related to activities that benefit multiple projects. Our estimates of research and development costs for clinical development programs are shown below:

	Year Ended December 31,		
Project Costs	**2006**	**2005**	**Increase (Decrease)**
		(In millions)	
ARCALYST™	$ 29.6	$ 57.2	$ (27.6)
Aflibercept	30.7	27.8	2.9
VEGF Trap-Eye	21.9	9.3	12.6
Other research programs & unallocated costs	54.9	61.3	(6.4)
Total research and development expenses	$ 137.1	$ 155.6	$ (18.5)

For the reasons described above under "Research and Development Expenses" for the years ended December 31, 2007 and 2006, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased to $8.1 million in 2006, compared to $9.6 million in 2005, primarily because we shipped less product to Merck in 2006.

General and Administrative Expenses:

General and administrative expenses increased to $25.9 million in 2006 from $25.4 million in the same period of 2005 as higher legal expenses related to general corporate matters and higher patent-and trademark-related costs were partly offset by lower professional fees for internal audit and other administrative advisory services and lower administrative facility costs.

Other Income and Expense:

In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble made a one-time $5.6 million payment to us, which we recognized as other contract income in 2005. In January 2005, we and sanofi-aventis amended our collaboration agreement to exclude rights to

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3187

Samsung Bioepis Exhibit 1017, pg. 3187

develop and commercialize aflibercept for intraocular delivery to the eye. In connection with the amendment, sanofi-aventis made a one-time $25.0 million payment to us, which we recognized as other contract income in 2005.

Investment income increased to $16.5 million in 2006 from $10.4 million in 2005, due primarily to higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock), as well as higher effective interest rates on investment securities in 2006. Interest expense was $12.0 million in 2006 and 2005. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, payments earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Bayer HealthCare, and Merck, and investment income.

Years Ended December 31, 2007 and 2006

At December 31, 2007, we had $846.3 million in cash, cash equivalents, restricted cash and marketable securities compared with $522.9 million at December 31, 2006. In connection with our non-exclusive license agreements with AstraZeneca and Astellas, as described above, AstraZeneca and Astellas each made an up-front payment to us of $20.0 million in February and April 2007, respectively. In August 2007, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in our Phase 3 study of the VEGF Trap-Eye in wet AMD. In December 2007, we received an $85.0 million upfront payment in connection with our new collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. Sanofi-aventis also purchased 12 million newly issued, unregistered shares of our Common Stock in December 2007 for gross proceeds to us of $312.0 million.

Cash Provided by Operations:

Net cash provided by operations was $27.4 million in 2007 and $23.1 million in 2006, and net cash used in operations was $30.3 million in 2005. Our net losses of $105.6 million in 2007, $102.3 million in 2006, and $95.4 million in 2005 included $28.1 million, $18.7 million, and $21.9 million, respectively, of non-cash stock-based employee compensation costs, consisting primarily of Stock Option Expense. Our net losses also included depreciation and amortization of $11.5 million, $14.6 million, and $15.5 million in 2007, 2006, and 2005, respectively, and a $5.9 million non-cash charge in 2007 related to marketable securities which we considered to be other than temporarily impaired in value.

In 2007, end-of-year accounts receivable increased by $10.8 million compared to 2006 due to higher receivable balances related to our collaborations with sanofi-aventis and Bayer HealthCare. Also, prepaid expenses and other assets increased $9.6 million at December 31, 2007 compared to end-of-year 2006 due primarily to higher prepaid clinical trial costs. At December 31, 2007, our deferred revenue balances increased by $89.8 million, compared to end-of-year 2006, due primarily to (i) the $85.0 million up-front payment received from sanofi-aventis, (ii) the $20.0 million milestone payment from Bayer HealthCare which was deemed to be non-substantive and fully deferred, and (iii) the two $20.0 million up-front payments received from each of AstraZeneca and Astellas, all as described above, partly offset by 2007 revenue recognition, principally from these deferred payments and prior year deferred payments from sanofi-aventis and Bayer HealthCare, in our Statement of Operations. Accounts payable, accrued expenses, and other liabilities increased $18.2 million at December 31, 2007 compared to end-of-year 2006 primarily due to a $4.9 million cost-sharing payment due to Bayer Healthcare in connection with the companies' VEGF Trap-Eye collaboration and higher accruals in 2007 for payroll costs and clinical-related expenses.

In 2006, end-of-year accounts receivable balances decreased by $29.0 million compared to 2005, due to the January 2006 receipt of a $25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, in connection with an amendment to our aflibercept collaboration to include Japan, and lower amounts due from sanofi aventis for reimbursement of aflibercept development expenses. Also, our deferred revenue balances at December 31, 2006 increased by $60.8 million compared to end-of-year 2005, due primarily to the October 2006 $75.0 million up-front payment from Bayer, as described above, partly offset by 2006 revenue

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3188

Samsung Bioepis Exhibit 1017, pg. 3188

recognition from deferred sanofi-aventis up-front payments. In 2005, our deferred revenue balances increased by $14.5 million compared to 2004, due primarily to the January 2006 $25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, partly offset by 2005 revenue recognition from deferred sanofi-aventis up-front payments.

The majority of our cash expenditures in 2007, 2006, and 2005 were to fund research and development, primarily related to our clinical programs and, in 2007, our preclinical human monoclonal antibody programs. In 2007, 2006, and 2005, we made two semi-annual interest payments totaling $11.0 million per year on our convertible senior subordinated notes.

Cash Provided by Investing Activities:

Net cash used in investing activities was $85.7 million in 2007 and $155.1 million in 2006, and net cash provided by investing activities was $115.5 million in 2005. In 2007 and 2006, purchases of marketable securities exceeded sales or maturities by $67.3 million and $150.7 million, respectively, whereas in 2005, sales or maturities of marketable securities exceeded purchases by $120.5 million. In addition, capital expenditures in 2007 included the purchase of land and a building in Rensselaer, NY for $9.0 million.

Cash Provided by Financing Activities:

Cash provided by financing activities was $319.4 million in 2007, $185.4 million in 2006, and $4.1 million in 2005. In 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of our Common Stock for gross proceeds to us of $312.0 million. In 2006, we completed a public offering of 7.6 million shares of our Common Stock and received proceeds, after expenses, of $174.6 million. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $7.6 million in 2007, $10.4 million in 2006, and $4.1 million in 2005.

Collaborations with the sanofi-aventis Group:

Aflibercept

Under our aflibercept collaboration agreement with sanofi-aventis, as described under "Collaborations" above, agreed upon worldwide aflibercept development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to $7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs. Since inception of the collaboration agreement through December 31, 2007, we and sanofi-aventis have incurred $306.8 million in agreed upon development expenses related to aflibercept. Currently, multiple clinical studies to evaluate aflibercept as both a single agent and in combination with other therapies in various cancer indications are ongoing, and we and sanofi-aventis plan to initiate additional aflibercept clinical studies in 2008.

Sanofi-aventis funded $38.3 million, $36.4 million, and $33.9 million, respectively, of our aflibercept development costs in 2007, 2006, and 2005, of which $10.5 million, $6.8 million, and $10.5 million, respectively, were included in accounts receivable as of December 31, 2007, 2006, and 2005. In addition, we received up-front payments of $80.0 million in September 2003 and $25.0 million in January 2006 from sanofi-aventis in connection with our collaboration. Both up-front payments were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2007, 2006, and 2005, we recognized $8.8 million, $11.4 million, and $9.5 million of revenue, respectively, related to these up-front payments.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3189

Samsung Bioepis Exhibit 1017, pg. 3189

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of aflibercept development expenses will terminate and we will retain all rights to aflibercept.

Antibodies

As part of the discovery agreement under our collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies, as described under "Collaborations" above, sanofi-aventis will fund up to $475.0 million of our research through December 31, 2012, subject to specified funding limits of $75.0 million for the period from the collaboration's inception through December 31, 2008, and $100.0 million annually in each of the next four years. The discovery agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

As part of the license agreement under the collaboration, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs (called Shared Phase 3 Trial Costs) for that drug candidate will be shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of $0.7 million as of December 31, 2007) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. The first therapeutic antibody to enter clinical development under the collaboration is REGN88, which has started clinical trials in rheumatoid arthritis. The second is expected to be a Dll4 antibody, which is currently slated to enter clinical development in mid-2008.

In 2007, sanofi-aventis funded $3.0 million of our expenses under the collaboration's discovery agreement and $0.7 million of our REGN88 development costs under the license agreement. These amounts were included in accounts receivable as of December 31, 2007. In addition, the $85.0 million up-front payment received from sanofi-aventis in December 2007 was recorded to deferred revenue and is being recognized as contract research and development revenue over the period during which we expect to perform services. In 2007, we recognized $0.9 million related to this up-front payment.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party and, in the case of the discovery agreement, a termination right for sanofi-aventis under certain circumstances, including if certain minimal criteria for the discovery program are not achieved. Prior to December 31, 2012, sanofi-aventis has the right to terminate the discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

Collaboration with Bayer HealthCare:

Under our collaboration agreement with Bayer HealthCare, as described under "Collaborations" above, agreed upon VEGF Trap-Eye development expenses incurred by both companies in 2007 under a global development plan, were shared as follows: The first $50.0 million was shared equally and we were solely responsible for up to the next $40.0 million. In 2007, cost-sharing between Bayer HealthCare and us of VEGF Trap-Eye development expenses resulted in (i) reimbursement of $14.3 million of our VEGF Trap-Eye development expenses by Bayer HealthCare,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3190

Samsung Bioepis Exhibit 1017, pg. 3190

of which $2.8 million was included in accounts receivable at December 31, 2007, and (ii) payment of $4.9 million of Bayer HealthCare VEGF Trap-Eye development expenses by us, which was included in accrued expenses at December 31, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

In 2008, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first $70.0 million will be shared equally, we are solely responsible for up to the next $30.0 million, and over $100.0 million will be shared equally. In 2009 and thereafter, all development expenses will be shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of $25.4 million as of December 31, 2007) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. In 2007, we and Bayer HealthCare initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. A second Phase 3 study of the VEGF Trap-Eye in wet AMD is planned for 2008.

We received a $75.0 million up-front payment in October 2006 and a $20.0 non-substantive milestone payment in August 2007 from Bayer HealthCare in connection with our collaboration. Both payments were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2007, we recognized $15.9 million of revenue related to these deferred payments. We did not recognize revenue in connection with our collaboration with Bayer HealthCare in 2006.

Bayer HealthCare has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

National Institutes of Health Grant:

Under our five-year grant from the NIH, as described under "Other Agreements" above, we are entitled to receive a minimum of $17.9 million over a five-year period, subject to compliance with the grant's terms and annual funding approvals, and another $1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2007 and 2006, we recognized $5.5 million and $0.5 million, respectively, of revenue related to the NIH Grant, of which $1.0 million and $0.5 million, respectively, was receivable at the end of 2007 and 2006. In 2008, we expect to receive funding of approximately $5 million for reimbursement of Regeneron expenses related to the NIH Grant.

License Agreement with AstraZeneca and Astellas:

Under these non-exclusive license agreements, AstraZeneca and Astellas each made a $20.0 million non-refundable, up-front payment to us in February and April 2007, respectively. AstraZeneca and Astellas are each required to make up to five additional annual payments of $20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the first three additional payments or earlier if the technology does not meet minimum performance criteria.

Severance Costs:

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the September 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions occurred in 2006 as we completed activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction were comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included $0.2 million of non-cash expenses. Estimated

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3191

Samsung Bioepis Exhibit 1017, pg. 3191

termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and 2006 workforce reductions were $2.6 million, of which $2.2 million was charged to expense in the fourth quarter of 2005 and $0.4 million was charged to expense in 2006.

Convertible Debt:

In 2001, we issued $200.0 million aggregate principal amount of convertible senior subordinated notes in a private placement and received proceeds, after deducting the initial purchasers' discount and out-of pocket expenses, of $192.7 million. The notes bear interest at 5.5% per annum, payable semi-annually, and mature in 2008. The notes are convertible into shares of our Common Stock at a conversion price of approximately $30.25 per share, subject to adjustment in certain circumstances. If the price per share of our Common Stock is above $30.25 at maturity, we would expect the notes would be converted into shares of Common Stock. Otherwise, we will be required to repay the $200.0 million aggregate principal amount of the notes or refinance the notes prior to maturity; however, we can provide no assurance that we will be able to successfully arrange such refinancing.

New Operating Lease — Tarrytown, New York Facilities:

We currently lease approximately 232,000 square feet of laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, we entered into a new operating lease agreement for approximately 221,000 square feet of laboratory and office space at our current Tarrytown location. The new lease includes approximately 27,000 square feet that we currently occupy (our retained facilities) and approximately 194,000 square feet to be located in new facilities that are under construction and expected to be completed in mid-2009. In 2007, we amended the December 2006 operating lease agreement to increase the amount of new space we will lease from approximately 194,000 square feet to approximately 230,000 square feet, for an amended total under the new lease of approximately 257,000 square feet. The term of the lease is now expected to commence in mid-2008 and will expire approximately 16 years later. Under the new lease we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, we issued a letter of credit in the amount of $1.6 million to our landlord, which is collateralized by a $1.6 million bank certificate of deposit.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $19.6 million in 2007, $3.3 million in 2006, and $4.7 million in 2005. In 2008, we expect to incur approximately $55 to $65 million in capital expenditures primarily in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our new Tarrytown operating lease, as described above. We expect that approximately $30 million of projected 2008 Tarrytown tenant improvement costs will be reimbursed by our landlord in connection with our new operating lease.

Funding Requirements:

Our total expenses for research and development from inception through December 31, 2007 have been approximately $1,352 million. We have entered into various agreements related to our activities to develop and commercialize product candidates and utilize our technology platforms, including collaboration agreements, such as those with sanofi-aventis and Bayer HealthCare, and agreements to use our *Velocigene* technology platform. We incurred expenses associated with these agreements, which include an allocable portion of general and administrative costs, of $108.2 million, $43.4 million, and $42.2 million in 2007, 2006, and 2005, respectively.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3192

Samsung Bioepis Exhibit 1017, pg. 3192

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55-65% of our expenditures for 2008 will be directed toward the preclinical and clinical development of product candidates, including ARCALYST™, aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88 and the Dll4 antibody); approximately 15-20% of our expenditures for 2008 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2008 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2007. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

		Payments Due by Period			
	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
			(In millions)		
Convertible senior subordinated notes payable (1)	$ 211.0	$ 211.0			
Operating leases (2)	253.0	5.1	$ 24.6	$ 29.7	$ 193.6
Purchase obligations (3)	125.9	60.4	65.5		
Total contractual obligations	$ 589.9	$ 276.5	$ 90.1	$ 29.7	$ 193.6

(1) Includes amounts representing interest.

(2) Includes projected obligations based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities under construction in Tarrytown, New York, as described above. Excludes future contingent rental costs for utilities, real estate taxes, and operating expenses. In 2007, these costs were $8.8 million.

(3) Purchase obligations primarily relate to (i) research and development commitments, including those related to clinical trials, (ii) capital expenditures for equipment acquisitions, and (iii) license payments. Our obligation to pay certain of these amounts may increase or be reduced based on certain future events. Open purchase orders for the acquisition of goods and services in the ordinary course of business are excluded from the table above.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare will share agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as described above. In addition, under our collaboration agreements with sanofi-aventis and Bayer HealthCare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi- aventis and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by sanofi-aventis and Bayer HealthCare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for our aflibercept collaboration with sanofi-aventis, royalties on product sales in Japan) otherwise payable to us unless we agree to reimburse these expenses at a faster rate at our option. Given the uncertainties related to drug development (including the development of aflibercept and co-developed antibody candidates in collaboration with sanofi-aventis and the VEGF Trap-Eye in collaboration with Bayer HealthCare) such as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer HealthCare will become profitable.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3193

Samsung Bioepis Exhibit 1017, pg. 3193

parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. Other than the $1.6 million letter of credit issued to our landlord in connection with our new operating lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of December 31, 2007, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

Revenue Recognition:

We recognize contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and Emerging Issues Task Force 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize our technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3194

Samsung Bioepis Exhibit 1017, pg. 3194

We enter into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. We may share the costs of research and development activities with our collaborator, such as in our VEGF Trap-Eye collaboration with Bayer HealthCare, or we may be reimbursed for all or a significant portion of the costs of our research and development activities, such as in our aflibercept and antibody collaborations with sanofi-aventis. We record our internal and third-party development costs associated with these collaborations as research and development expenses. When we are entitled to reimbursement of all or a portion of the research and development expenses that we incur under a collaboration, we record those reimbursable amounts as contract research and development revenue proportionately as we recognize our expenses. If the collaboration is a cost-sharing arrangement in which both we and our collaborator perform development work and share costs, in periods when our collaborator incurs development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of the collaborator's development expenses that we are obligated to reimburse. In addition, we record revenue in connection with a government research grant using a proportional performance model as we incur expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are possible, and could result in material changes to the amount of revenue recognized each year in the future. In addition, performance periods may be extended if development programs encounter delays or we and our collaborators decide to expand our clinical plans for a drug candidate into additional disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination. For the year ended December 31, 2006, changes in estimates of our performance periods, including an extension of our estimated performance period for our aflibercept collaboration with sanofi-aventis, did not have a material impact on contract research and development revenue that we recognized. For the year ended December 31, 2007, we recognized $2.6 million less in contract research and development revenue, compared to amounts recognized in 2006, in connection with $105.0 million of non-refundable up-front payments previously received from sanofi-aventis pursuant to the companies' aflibercept collaboration, due to an extension of our estimated performance period.

Clinical Trial Expenses:

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations (CROs). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 15% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts with CROs are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3195

Samsung Bioepis Exhibit 1017, pg. 3195

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the years ended December 31, 2007 or 2006.

Depreciation of Property, Plant, and Equipment:

Property, plant, and equipment are stated at cost. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	7-30 years
Laboratory and computer equipment	3-5 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

In some situations, the life of the asset may be extended or shortened if circumstances arise that would lead us to believe that the estimated life of the asset has changed. The life of leasehold improvements may change based on the extension of lease contracts with our landlords. Changes in the estimated lives of assets will result in an increase or decrease in the amount of depreciation recognized in future periods.

Stock-based Employee Compensation:

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date. Prior to the adoption of the fair value method, we accounted for stock-based compensation to employees under the intrinsic value method of accounting set forth in APB 25, *Accounting for Stock Issued to Employees*, and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period operating results have not been restated.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3196

Samsung Bioepis Exhibit 1017, pg. 3196

time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005, and prior to our adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that were not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by $0.8 million and is included in our operating results for the year ended December 31, 2006 as a cumulative-effect adjustment of a change in accounting principle.

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

Future Impact of Recently Issued Accounting Standards

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, however on December 14, 2007, the FASB issued a proposed staff position (FSP FAS 157-b) which would delay the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. We are required to adopt SFAS 157 as it relates to our financial assets and financial liabilities effective for the fiscal year beginning January 1, 2008, and as it relates to our nonfinancial assets and nonfinancial liabilities for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of SFAS 157 will have a material impact on our financial statements.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Our management does not anticipate that the adoption of SFAS 159 will have a material impact on our financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We are required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Our management does not anticipate that the adoption of EITF 07-3 will have a material impact on our financial statements.

Item 7A. ***Quantitative and Qualitative Disclosure About Market Risk***

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate, asset-backed, and U.S. government securities.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3197

Samsung Bioepis Exhibit 1017, pg. 3197

We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in approximately a $1.9 million and $1.7 million decrease in the fair value of our investment portfolio at December 31, 2007 and 2006, respectively. The increase in the potential impact of an interest rate change at December 31, 2007, compared to December 31, 2006, is due primarily to slight increases in our investment portfolio's duration to maturity at the end of 2007 versus the end of 2006.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. In 2007, we recognized a $5.9 million charge related to marketable securities which we considered to be other than temporarily impaired in value.

Item 8. ***Financial Statements and Supplementary Data***

The financial statements required by this Item are included on pages F-1 through F-38 of this report. The supplementary financial information required by this Item is included at pages F-37 and F-38 of this report.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation our management has concluded that our internal control over financial reporting was effective as of December 31, 2007. The effectiveness of our internal control over financial reporting as of December 31, 2007 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3198

Samsung Bioepis Exhibit 1017, pg. 3198

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors and Executive Officers and Corporate Governance***

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included under the captions "Election of Directors," "Board Committees and Meetings," "Executive Officers of the Company," and "Section 16(a) Beneficial Ownership Reporting Compliance," in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our officers, directors and employees. The full text of our code of business conduct and ethics can be found on the Company's website (http://www.regn.com) under the Investor Relations heading.

Item 11. ***Executive Compensation***

The information called for by this item will be included under the captions "Compensation Committee Report," "Compensation Committee Interlocks and Insider Participation," "Executive Compensation" and "Compensation of Directors" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information called for by this item will be included under the captions "Equity Compensation Plan Information", "Security Ownership of Management" and "Stock Ownership of Certain Beneficial Owners" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item will be included under the captions "Elections of Directors" and "Review of Transactions with Related Persons" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 14. ***Principal Accountant Fees and Services***

The information called for by this item will be included under the caption "Information about Fees Paid to Independent Registered Public Accounting Firm" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) *1. Financial Statements*

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3199

Samsung Bioepis Exhibit 1017, pg. 3199

The financials statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and therefore have been omitted.

3. Exhibits

Exhibit Number			Description
3.1		—	Restated Certificate of Incorporation, filed February 11, 2008 with the New York Secretary of State.
3.2	(a)	—	By-Laws of the Company, currently in effect (amended through November 9, 2007).
10.1	(b)	—	1990 Amended and Restated Long-Term Incentive Plan.
10.2	(c)	—	2000 Long-Term Incentive Plan.
10.3.1	(d)	—	Amendment No. 1 to 2000 Long-Term Incentive Plan, effective as of June 14, 2002.
10.3.2	(d)	—	Amendment No. 2 to 2000 Long-Term Incentive Plan, effective as of December 20, 2002.
10.3.3	(e)	—	Amendment No. 3 to 2000 Long-term Incentive Plan, effective as of June 14, 2004.
10.3.4	(f)	—	Amendment No. 4 to 2000 Long-term Incentive Plan, effective as of November 15, 2004.
10.3.5	(g)	—	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10.3.6	(g)	—	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.3.7	(h)	—	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.4	(d)	—	Employment Agreement, dated as of December 20, 2002, between the Company and Leonard S. Schleifer, M.D., Ph.D.
10.5*	(i)	—	Employment Agreement, dated as of December 31, 1998, between the Company and P. Roy Vagelos, M.D.
10.6	(j)	—	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, effective as of February 1, 2006.
10.7	(k)	—	Indenture, dated as of October 17, 2001, between Regeneron Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, as trustee.
10.8	(k)	—	Registration Rights Agreement, dated as of October 17, 2001, among Regeneron Pharmaceuticals, Inc., Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Robertson Stephens, Inc.
10.9*	(l)	—	IL-1 License Agreement, dated June 26, 2002, by and among the Company, Immunex Corporation, and Amgen Inc.
10.10*	(m)	—	Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
10.11*	(n)	—	Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.11.1*	(i)	—	Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 31, 2004.
10.11.2	(o)	—	Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of January 7, 2005.
10.11.3*	(p)	—	Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 21, 2005.
10.11.4*	(p)	—	Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals, Inc.) and Regeneron Pharmaceuticals, Inc., effective as of January 31, 2006.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3200

Samsung Bioepis Exhibit 1017, pg. 3200

Exhibit Number			Description
10.12	(n)	—	Stock Purchase Agreement, dates as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.13*	(q)	—	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
10.14*	(r)	—	Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007 by and between AstraZeneca UK Limited and Regeneron Pharmaceuticals, Inc.
10.15	(s)	—	Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc.
10.16*	(t)	—	Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
10.17*	(u)	—	First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
10.18*		—	Discovery and Preclinical Development Agreement, dated as of November 28, 2007, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.19*		—	License and Collaboration Agreement, dated as of November 28, 2007, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique Du Nord and Regeneron Pharmaceuticals, Inc.
10.20		—	Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique Du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.
10.21		—	Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and Regeneron Pharmaceuticals, Inc.
12.1		—	Statement re: computation of ratio of earnings to combined fixed charges of Regeneron Pharmaceuticals, Inc.
23.1		—	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1		—	Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2		—	Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32		—	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

(a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.

(b) Incorporated by reference from the Company's registration statement on Form S-1 (file number 33-39043).

(c) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2001, filed March 22, 2002.

(d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2002, filed March 31, 2003.

(e) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2004, filed August 5, 2004.

(f) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 17, 2004.

(g) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.

(h) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.

(i) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2004, filed March 11, 2005.

(j) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 25, 2006.

(k) Incorporated by reference from the Company's registration statement on Form S-3 (file number 333-74464).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3201

Samsung Bioepis Exhibit 1017, pg. 3201

(l) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.

(m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.

(n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 11, 2003.

(o) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.

(p) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2005, filed February 28, 2006.

(q) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed October 18, 2006.

(r) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2006, filed March 12, 2007.

(s) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.

(t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended March 31, 2007, filed May 4, 2007.

(u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended September 31, 2007, filed November 7, 2007.

---

* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3202

Samsung Bioepis Exhibit 1017, pg. 3202

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

By: /s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Dated: New York, New York
February 27, 2008

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Murray A. Goldberg, Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, and each of them, his true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title
/s/ LEONARD S. SCHLEIFER Leonard S. Schleifer, M.D., Ph.D.	President, Chief Executive Officer, and Director (Principal Executive Officer)
/s/ MURRAY A. GOLDBERG Murray A. Goldberg	Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer)
/s/ DOUGLAS S. MCCORKLE Douglas S. McCorkle	Vice President, Controller and Assistant Treasurer (Principal Accounting Officer)
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D	Executive Vice President, Chief Scientific Officer, President, Regeneron Research Laboratories, and Director
/s/ P. ROY VAGELOS P. Roy Vagelos, M.D.	Chairman of the Board
/s/ CHARLES A. BAKER Charles A. Baker	Director

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3203

Samsung Bioepis Exhibit 1017, pg. 3203

Signature	Title
/s/ MICHAEL S. BROWN Michael S. Brown, M.D.	Director
/s/ ALFRED G. GILMAN Alfred G. Gilman, M.D., Ph.D.	Director
/s/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	Director
/s/ ARTHUR F. RYAN Arthur F. Ryan	Director
/s/ GEORGE L. SING George L. Sing	Director

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3204

Samsung Bioepis Exhibit 1017, pg. 3204

REGENERON PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

	Page Numbers
REGENERON PHARMACEUTICALS, INC.	
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets at December 31, 2007 and 2006	F-3
Statements of Operations for the years ended December 31, 2007, 2006, and 2005	F-4
Statements of Stockholders' Equity for the years ended December 31, 2007, 2006, and 2005	F-5 to F-6
Statements of Cash Flows for the years ended December 31, 2007, 2006, and 2005	F-7
Notes to Financial Statements	F-8 to F-38

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3205

Samsung Bioepis Exhibit 1017, pg. 3205

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Regeneron Pharmaceuticals, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control — Integrated* Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in note 2 to the financial statements, effective January 1, 2006, the Company changed its method of accounting for share-based payment, to conform with FASB Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-based Payment."

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP

New York, New York
February 27, 2008

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3206

Samsung Bioepis Exhibit 1017, pg. 3206

REGENERON PHARMACEUTICALS, INC.

BALANCE SHEETS
December 31, 2007 and 2006

	2007	2006
	(In thousands, except share data)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 498,925	$ 237,876
Marketable securities	267,532	221,400
Accounts receivable from the sanofi-aventis Group	14,244	6,900
Accounts receivable — other	4,076	593
Prepaid expenses and other current assets	13,052	3,215
Total current assets	797,829	469,984
Restricted cash	1,600	1,600
Marketable securities	78,222	61,983
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	58,304	49,353
Other assets	303	2,170
Total assets	$ 936,258	$ 585,090
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 39,232	$ 21,471
Deferred revenue from sanofi-aventis, current portion	18,855	8,937
Deferred revenue — other, current portion	25,577	14,606
Notes payable	200,000	
Total current liabilities	283,664	45,014
Deferred revenue from sanofi-aventis	126,431	61,013
Deferred revenue — other	65,896	62,439
Notes payable		200,000
Total liabilities	475,991	368,466
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding — none		
Class A Stock, convertible, $.001 par value: 40,000,000 shares authorized; shares issued and outstanding — 2,260,266 in 2007 and 2,270,353 in 2006	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding — 76,592,218 in 2007 and 63,130,962 in 2006	77	63
Additional paid-in capital	1,253,235	904,407
Accumulated deficit	(793,217)	(687,617)
Accumulated other comprehensive income (loss)	170	(231)
Total stockholders' equity	460,267	216,624
Total liabilities and stockholders' equity	$ 936,258	$ 585,090

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3207

Samsung Bioepis Exhibit 1017, pg. 3207

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2007, 2006, and 2005

	2007	2006	2005
	(In thousands, except per share data)		
Revenues			
Contract research and development from sanofi-aventis	$ 51,687	$ 47,763	$ 43,445
Other contract research and development	44,916	3,373	9,002
Contract manufacturing		12,311	13,746
Technology licensing	28,421		
	125,024	63,447	66,193
Expenses			
Research and development	201,613	137,064	155,581
Contract manufacturing		8,146	9,557
General and administrative	37,865	25,892	25,476
	239,478	171,102	190,614
Loss from operations	(114,454)	(107,655)	(124,421)
Other income (expense)			
Other contract income (includes $25.0 million from sanofi-aventis)			30,640
Investment income	20,897	16,548	10,381
Interest expense	(12,043)	(12,043)	(12,046)
	8,854	4,505	28,975
Net loss before cumulative effect of a change in accounting principle	(105,600)	(103,150)	(95,446)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")		813	
Net loss	$ (105,600)	$ (102,337)	$ (95,446)
Net loss per share, basic and diluted:			
Net loss before cumulative effect of a change in accounting principle	$ (1.59)	$ (1.78)	$ (1.71)
Cumulative effect of adopting SFAS 123R		0.01	
Net loss	$ (1.59)	$ (1.77)	$ (1.71)
Weighted average shares outstanding, basic and diluted	66,334	57,970	55,950

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3208

Samsung Bioepis Exhibit 1017, pg. 3208

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2007, 2006, and 2005

	Class A Stock		Common Stock		Additional Paid-in	Unearned	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Compensation	Deficit	Income (Loss)	Equity	Income (Loss)
						(In thousands)				
Balance, December 31, 2004	2,358	$ 2	53,502	$ 54	$675,389	$ (2,299)	$ (489,834)	$ (769)	$ 182,543	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			494		4,081				4,081	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			90		632				632	
Conversion of Class A Stock to Common Stock	(11)		11							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(5)		(54)	54				
Stock-based compensation expense					19,963	1,930			21,893	
Net loss, 2005							(95,446)		(95,446)	$ (95,446)
Change in net unrealized gain (loss) on marketable securities								299	299	299
Balance, December 31, 2005	2,347	2	54,092	54	700,011	(315)	(585,280)	(470)	114,002	$ (95,147)
Issuance of Common Stock in a public offering at $23.03 per share			7,600	8	175,020				175,028	
Cost associated with issuance of equity securities					(412)				(412)	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			1,243	1	10,391				10,392	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			121		1,884				1,884	
Conversion of Class A Stock to Common Stock	(77)		77							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(2)							
Stock-based compensation expense					18,641				18,641	
Adjustment to reduce unearned compensation upon adoption of SFAS 123R					(315)	315				
Cumulative effect of adopting SFAS 123R					(813)				(813)	
Net loss, 2006							(102,337)		(102,337)	$ (102,337)
Change in net unrealized gain (loss) on marketable securities								239	239	239
Balance, December 31, 2006	2,270	2	63,131	63	904,407	—	(687,617)	(231)	216,624	$ (102,098)

(Continued)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3209

Samsung Bioepis Exhibit 1017, pg. 3209

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY — (Continued)
For the Years Ended December 31, 2007, 2006, and 2005

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Comprehensive Income (Loss)
	Shares	Amount	Shares	Amount		(In thousands)				
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			886	1	7,618				7,619	
Issuance of Common Stock to sanofi-aventis			12,000	12	311,988				312,000	
Cost associated with issuance of equity securities to sanofi-aventis					(219)				(219)	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			65		1,367				1,367	
Issuance of restricted Common Stock under Long- Term Incentive Plan			500	1	(1)					
Conversion of Class A Stock to Common Stock	(10)		10							
Stock-based compensation expense					28,075				28,075	
Net loss, 2007							(105,600)		(105,600)	$ (105,600)
Change in net unrealized gain (loss) on marketable securities								401	401	401
Balance, December 31, 2007	2,260	$ 2	76,592	$ 77	$1,253,235	—	$ (793,217)	$ 170	$ 460,267	$ (105,199)

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3210

Samsung Bioepis Exhibit 1017, pg. 3210

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2007, 2006, and 2005

	2007	2006	2005
		(In thousands)	
Cash flows from operating activities			
Net loss	$ (105,600)	$ (102,337)	$ (95,446)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities			
Depreciation and amortization	11,487	14,592	15,504
Non-cash compensation expense	28,075	18,675	21,859
Impairment charge on marketable securities	5,943		
Cumulative effect of a change in accounting principle		(813)	
Changes in assets and liabilities			
(Increase) decrease in accounts receivable	(10,827)	29,028	6,581
(Increase) decrease in prepaid expenses and other assets	(9,649)	155	74
Decrease in inventory		3,594	1,250
Increase in deferred revenue	89,764	60,833	14,469
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	18,179	(652)	5,413
Total adjustments	132,972	125,412	65,150
Net cash provided by (used in) operating activities	27,372	23,075	(30,296)
Cash flows from investing activities			
Purchases of marketable securities	(594,446)	(456,893)	(102,990)
Sales or maturities of marketable securities	527,169	306,199	223,448
Capital expenditures	(18,446)	(2,811)	(4,964)
Increase in restricted cash		(1,600)	
Net cash (used in) provided by investing activities	(85,723)	(155,105)	115,494
Cash flows from financing activities			
Net proceeds from the issuance of Common Stock	319,400	185,008	4,081
Other		390	
Net cash provided by financing activities	319,400	185,398	4,081
Net increase in cash and cash equivalents	261,049	53,368	89,279
Cash and cash equivalents at beginning of period	237,876	184,508	95,229
Cash and cash equivalents at end of period	$ 498,925	$ 237,876	$ 184,508
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 11,000	$ 11,000	$ 11,002

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3211

Samsung Bioepis Exhibit 1017, pg. 3211

1. Organization and Business

Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") was incorporated in January 1988 in the State of New York. The Company is engaged in research and development programs to discover and commercialize therapeutics to treat human disorders and conditions. The Company's facilities are located in New York. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, obtaining regulatory approvals, commercializing products, and obtaining and enforcing patents.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

For purposes of the statement of cash flows and the balance sheet, the Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	7-30 years
Laboratory and computer equipment	3-5 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

Accounting for the Impairment of Long-Lived Assets

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount in accordance with Statement of Financial Accounting Standards No. ("SFAS") 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. For all periods presented, no impairment losses were recorded.

Patents

As a result of the Company's research and development efforts, the Company has obtained, applied for, or is applying for, a number of patents to protect proprietary technology and inventions. All costs associated with patents are expensed as incurred.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3212

Samsung Bioepis Exhibit 1017, pg. 3212

Revenue Recognition

a. Contract Research and Development and Research Progress Payments

The Company recognizes contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* ("SAB 104") and Emerging Issues Task Force 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). The Company earns contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, such as in the Company's VEGF Trap-Eye collaboration with Bayer HealthCare LLC, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities, such as in the Company's aflibercept and antibody collaborations with sanofi-aventis. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as contract research and development revenue proportionately as the Company recognizes its expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, in periods when the Company's collaborator incurs development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of the collaborator's development expenses that the Company is obligated to reimburse. In addition, the Company records revenue in connection with a government research grant using a proportional performance model as it incurs expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are possible, and could result in material changes to the amount of revenue recognized each year in the future. In addition, performance periods may be extended if the Company and its collaborators decide to expand the clinical plans for a drug candidate into

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3213

Samsung Bioepis Exhibit 1017, pg. 3213

additional disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, the Company would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

b. Contract Manufacturing

The Company manufactured product and performed services for a third party under a contract manufacturing agreement which expired in October 2006. Contract manufacturing revenue was recognized as product was shipped and as services were performed (see Note 13).

c. Technology Licensing

The Company enters into non-exclusive license agreements with third parties that allow the third party to utilize the Company's *VelocImmune*® technology in its internal research programs. The terms of these agreements include annual, non-refundable, up-front payments and entitle the Company to receive royalties on any future sales of products discovered by the third party using the Company's *VelocImmune* technology (see Note 12). Annual, non-refundable, up-front payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective annual license periods.

Investment Income

Interest income, which is included in investment income, is recognized as earned.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements (see Note 10), the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur (see Note 11), expenses related to the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by contract research organizations ("CROs"). CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 15% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of the Company's contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3214

Samsung Bioepis Exhibit 1017, pg. 3214

activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates. The Company's estimates and assumptions for clinical expense recognition could differ significantly from its actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

Per Share Data

Net income (loss) per share, basic and diluted, is computed on the basis of the net income (loss) for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock outstanding, and of common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the treasury stock method when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's outstanding convertible senior subordinated notes, which are included under the if-converted method when dilutive. The computation of diluted net loss per share for the years ended December 31, 2007, 2006, and 2005 does not include common stock equivalents, since such inclusion would be antidilutive. Disclosures required by SFAS 128, *Earnings per Share*, have been included in Note 19.

Income Taxes

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain. See Note 17.

Comprehensive Income (Loss)

The Company presents comprehensive income (loss) in accordance with SFAS 130, *Reporting Comprehensive Income.* Comprehensive income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive income (loss) is immaterial. Comprehensive losses for the years ended December 31, 2007, 2006, and 2005 have been included in the Statements of Stockholders' Equity.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3215

Samsung Bioepis Exhibit 1017, pg. 3215

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities, and receivables from sanofi-aventis and Bayer HealthCare. The Company generally invests its excess cash in obligations of the U.S. government and its agencies, investment grade debt securities issued by corporations, governments, and financial institutions, bank deposits, asset-backed securities, commercial paper, and money market funds that invest in these instruments. The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject the Company to the risk of not being able to recover the full principal value of the security. The Company recognizes a charge to earnings in a period when the Company considers a marketable security to be other than temporarily impaired in value.

Risks and Uncertainties

Regeneron has had no sales of its products and there is no assurance that the Company's research and development efforts will be successful, that the Company will ever have commercially approved products, or that the Company will achieve significant sales of any such products. The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) payments from the Company's collaborators and other entities for the Company's development activities with respect to product candidates and to utilize the Company's technology platforms, (ii) payments for past contract manufacturing activities, and (iii) investment income. The Company operates in an environment of rapid change in technology and is dependent upon the services of its employees, consultants, collaborators, and certain third-party suppliers, including single-source unaffiliated third-party suppliers of certain raw materials and equipment. Regeneron, as licensee, licenses certain technologies that are important to the Company's business which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate the Company's licenses.

Contract research and development revenue in 2007 was primarily earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 11 for the terms of these agreements). The Company recognizes revenue from its collaborations with sanofi-aventis and Bayer HealthCare in accordance with SAB 104 and EITF 00-21, as described above. These collaboration agreements contain early termination provisions, as defined, by sanofi-aventis or Bayer HealthCare, as applicable.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Significant estimates include (i) useful lives of property, plant, and equipment, (ii) the periods over which certain revenues and expenses will be recognized, including contract research and development revenue recognized from non-refundable licensing payments and expense recognition of certain clinical trial costs which are included in research and development expenses, (iii) the extent to which deferred tax assets and liabilities are offset by a valuation allowance, and (iv) the fair value of stock options on their date of grant using the Black-Scholes option-pricing model, based on assumptions with respect to (a) expected volatility of our Common Stock price, (b) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (c) expected dividend yield on the Company's Common Stock, and (d) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. In addition, in connection with the recognition of compensation expense in accordance with the provisions of SFAS 123R, *Share-*

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3216

Samsung Bioepis Exhibit 1017, pg. 3216

Based Payment, as described below, the Company is required to estimate, at the time of grant, the number of stock option awards that are expected to be forfeited.

Stock-based Employee Compensation

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 (including replacement options granted under the Company's stock option exchange program which concluded on January 5, 2005 (see Note 14)) and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate, at the time of grant, the number of awards that are expected to be forfeited and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005 and prior to the Company's adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that were not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by $0.8 million and is included in the Company's operating results in 2006 as a cumulative-effect adjustment of a change in accounting principle.

For the years ended December 31, 2007, 2006, and 2005, $28.0 million, $18.4 million, and $19.9 million, respectively, of non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") was recognized in operating expenses. In addition, for the year ended December 31, 2005, $0.1 million of Stock Option Expense was capitalized in inventory.

Other disclosures required by SFAS 123 and SFAS 123R have been included in Note 14.

Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

In 2007, 2006, and 2005, the Company recognized $0.1 million, $0.3 million, and $1.9 million, respectively, of compensation expense related to Restricted Stock awards, the fair value of which is expensed, on a pro rata basis, over the period that the restrictions on the shares lapse (see Note 14).

Included in accounts payable and accrued expenses at December 31, 2007, 2006, and 2005 were $1.7 million, $0.8 million, and $0.2 million of capital expenditures, respectively.

Included in accounts payable and accrued expenses at December 31, 2006, 2005, and 2004 were $1.4 million, $1.9 million, and $0.6 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2007, 2006, and 2005, the Company contributed 64,532, 120,960, and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3217

Samsung Bioepis Exhibit 1017, pg. 3217

Included in marketable securities at December 31, 2007, 2006, and 2005 were $2.2 million, $1.5 million, and $1.2 million of accrued interest income, respectively.

Future Impact of Recently Issued Accounting Standards

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles ("GAAP"), and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, however on December 14, 2007, the FASB issued a proposed staff position ("FSP FAS 157-b") which would delay the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The Company is required to adopt SFAS 157 as it relates to the Company's financial assets and financial liabilities effective for the fiscal year beginning January 1, 2008, and as it relates to the Company's nonfinancial assets and nonfinancial liabilities for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of SFAS 157 will have a material impact on the Company's financial statements.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Management does not anticipate that the adoption of SFAS 159 will have a material impact on the Company's financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company is required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Management does not anticipate that the adoption of EITF 07-3 will have a material impact on the Company's financial statements.

3. Severance Costs

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions occurred during 2006 as the Company completed activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction were comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included non-cash expenses due to the accelerated vesting of certain stock options and restricted stock held by affected employees. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and were expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for*

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3218

Samsung Bioepis Exhibit 1017, pg. 3218

Costs Associated with Exit or Disposal Activities. The total costs associated with the 2005 and 2006 workforce reductions were $2.6 million, including $0.2 million of non-cash expenses.

Severance costs associated with the workforce reduction plan that were charged to expense in 2005, 2006, and 2007 consist of the following:

	Costs charged to expense in 2005	Costs paid or settled in 2005	Accrued liability at December 31, 2005
Employee severance, payroll taxes, and benefits	$ 1,786	$ 879	$ 907
Other severance costs	206	30	176
Non-cash expenses	221	221	
Total	$ 2,213	$ 1,130	$ 1,083

	Costs charged to expense 2006	Costs paid or settled in 2006	Accrued liability at December 31, 2006
Employee severance, payroll taxes, and benefits	$ 315	$ (1,159)	$ 63
Other severance costs	33	(209)	
Total	$ 348	$ (1,368)	$ 63

	Costs charged to expense in 2007	Costs paid or settled in 2007	Accrued liability at December 31, 2007
Employee severance, payroll taxes, and benefits	$ 43	$ (106)	$ —

These severance costs are included in the Company's Statement of Operations for the years ended December 31, 2007, 2006, and 2005 as follows:

	2007	2006		2005	
	R&D	R&D	G&A	R&D	G&A
Employee severance, payroll taxes, and benefits	$ 43	$ 317	$ (2)	$ 1,734	$ 52
Other severance costs		33		206	
Non-cash expenses				215	6
Total	$ 43	$ 350	$ (2)	$ 2,155	$ 58

For segment reporting purposes (see Note 20), all severance-related expenses are included in the Research & Development segment.

4. Marketable Securities

The Company considers its unrestricted marketable securities to be "available-for-sale," as defined by SFAS 115, *Accounting for Certain Investments in Debt and Equity Securities*. Gross unrealized holding gains and losses are reported as a net amount in a separate component of stockholders' equity entitled Accumulated Other Comprehensive Income (Loss). The net change in unrealized holding gains and losses is excluded from operations and included in stockholders' equity as a separate component of comprehensive loss.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3219

Samsung Bioepis Exhibit 1017, pg. 3219

The following tables summarize the amortized cost basis of marketable securities, the aggregate fair value of marketable securities, and gross unrealized holding gains and losses at December 31, 2007 and 2006:

	Amortized Cost Basis	Fair Value	Unrealized Holding Gains	Unrealized Holding (Losses)	Unrealized Holding Net
At December 31, 2007					
Maturities within one year					
Corporate and municipal bonds	$ 69,213	$ 69,263	$ 74	$ (24)	$ 50
Asset-backed securities	73,939	73,706	99	(332)	(233)
Commercial paper	64,846	64,870	25	(1)	24
U.S. government obligations	50,386	50,475	89		89
Certificates of deposit	9,220	9,218		(2)	(2)
	267,604	267,532	287	(359)	(72)
Maturities between one and two years					
Corporate and municipal bonds	49,724	49,947	289	(66)	223
Asset-backed securities	20,295	20,323	173	(145)	28
Commercial paper	7,952	7,952			
	77,971	78,222	462	(211)	251
	$ 345,575	$ 345,754	$ 749	$ (570)	$ 179
At December 31, 2006					
Maturities within one year					
Corporate and municipal bonds	$ 25,254	$ 25,221		$ (33)	$ (33)
Asset-backed securities	94,159	94,075	$ 6	(90)	(84)
Commercial paper	69,547	69,535	9	(21)	(12)
U.S. government obligations	22,267	22,243	1	(25)	(24)
Certificates of deposit	10,327	10,326	2	(3)	(1)
	221,554	221,400	18	(172)	(154)
Maturities between one and two years					
Corporate and municipal bonds	6,047	6,032		(15)	(15)
Asset-backed securities	32,835	32,762	3	(76)	(73)
U.S. government obligations	23,190	23,189	6	(7)	(1)
	62,072	61,983	9	(98)	(89)
	$ 283,626	$ 283,383	$ 27	$ (270)	$ (243)

In addition, cash equivalents at December 31, 2007 and 2006 included an unrealized holding loss of $9 thousand and an unrealized holding gain of $12 thousand, respectively.

Realized gains and losses are included as a component of investment income. For the years ended December 31, 2007, 2006, and 2005, gross realized gains and losses on sales of marketable securities was not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the securities, adjusted for the amortization of any discount or premium. In 2007, deterioration in the credit quality of marketable securities from two issuers

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3220

Samsung Bioepis Exhibit 1017, pg. 3220

has subjected the Company to the risk of not being able to recover the full principal value of these securities, which totals $14.0 million. Since market activity for these securities is very limited, their fair values at December 31, 2007 were developed based on information provided by the Company's investment advisors, including but not limited to estimated value of the assets underlying each security and quoted bid prices, as applicable. As a result, the Company recognized a $5.9 million charge related to these marketable securities, which the Company considered to be other than temporarily impaired. Excluding these other than temporarily impaired securities, fair value of marketable securities has been estimated based on inputs that are observable for each security, either directly or indirectly, through corroboration with observable market data.

The following table shows the unrealized losses and fair value of the Company's marketable securities with unrealized losses that are deemed to be only temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2007 and 2006. The securities listed at December 31, 2007 mature at various dates through December 2009.

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
At December 31, 2007						
Corporate and municipal bonds	$ 36,979	$ (89)	$ 3,056	$ (1)	$ 40,035	$ (90)
Asset-backed securities	18,674	(360)	12,390	(116)	31,064	(476)
Commercial paper	14,950	(2)			14,950	(2)
Certificates of deposit	9,218	(2)			9,218	(2)
	$ 79,821	$ (453)	$ 15,446	$ (117)	$ 95,267	$ (570)
At December 31, 2006						
Corporate and municipal bonds	$ 12,113	$ (31)	$ 12,191	$ (18)	$ 24,304	$ (49)
Asset-backed securities	92,544	(161)	891	(5)	93,435	(166)
Commercial paper	12,949	(20)			12,949	(20)
U.S. government obligations	23,273	(25)	2,023	(7)	25,296	(32)
Certificates of deposit	3,034	(3)			3,034	(3)
	$ 143,913	$ (240)	$ 15,105	$ (30)	$ 159,018	$ (270)

At December 31, 2007, the unrealized losses in the Company's marketable securities were primarily caused by general instability in the credit markets at the end of 2007. At December 31, 2006, the unrealized losses in the Company's marketable securities were primarily caused by interest rate increases, which generally resulted in a decrease in the market value of the Company's portfolio. Based upon the Company's currently projected sources and uses of cash, the Company intends to hold these securities until a recovery of fair value, which may be maturity. Therefore, the Company does not consider these marketable securities at December 31, 2007 and 2006 to be other than temporarily impaired. However, further deterioration in the credit markets may subject the Company to the risk of not being able to recover the full principal value of certain of its marketable securities, which could have a material impact on the Company's financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3221

Samsung Bioepis Exhibit 1017, pg. 3221

5. Accounts Receivable

Accounts receivable as of December 31, 2007 and 2006 consist of the following:

	2007	2006
Receivable from sanofi-aventis (see Note 11)	$ 14,244	$ 6,900
Receivable from Bayer HealthCare (see Note 11)	2,797	
Other	1,279	593
	$ 18,320	$ 7,493

6. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2007 and 2006 consist of the following:

	2007	2006
Land	$ 2,117	$ 475
Building and improvements	66,208	57,045
Leasehold improvements	13,982	14,662
Construction-in-progress	4,677	203
Laboratory and other equipment	61,717	59,164
Furniture, fixtures, software and computer equipment	6,080	5,413
	154,781	136,962
Less, accumulated depreciation and amortization	(96,477)	(87,609)
	$ 58,304	$ 49,353

In October 2007, the Company purchased land and a building in Rensselaer, New York for $9.0 million. The Company previously leased manufacturing, office, and warehouse space in a portion of the purchased building (see Note 10).

Depreciation and amortization expense on property, plant, and equipment amounted to $10.4 million, $14.3 million, and $15.4 million for the years ended December 31, 2007, 2006, and 2005, respectively. Included in these amounts was $0.7 million and $0.9 million of depreciation and amortization expense related to contract manufacturing that was capitalized into inventory for the years ended December 31, 2006 and 2005, respectively.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2007 and 2006 consist of the following:

	2007	2006
Accounts payable	$ 8,128	$ 4,349
Payable due to Bayer HealthCare (see Note 11)	4,892	
Accrued payroll and related costs	14,514	9,932
Accrued clinical trial expense	5,609	2,606
Accrued expenses, other	3,797	2,292
Interest payable on convertible notes	2,292	2,292
	$ 39,232	$ 21,471

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3222

Samsung Bioepis Exhibit 1017, pg. 3222

8. Deferred Revenue

Deferred revenue as of December 31, 2007 and 2006 consists of the following:

	2007	2006
Current portion:		
Received from sanofi-aventis (see Note 11)	$ 18,855	$ 8,937
Received from Bayer HealthCare (see Note 11)	13,179	12,561
Received for technology license agreements (see Note 12)	11,579	
Other	819	2,045
	$ 44,432	$ 23,543
Long-term portion:		
Received from sanofi-aventis	$ 126,431	$ 61,013
Received from Bayer HealthCare	65,896	62,439
	$ 192,327	$ 123,452

9. Stockholders Equity

The Company's Restated Certificate of Incorporation provides for the issuance of up to 40 million shares of Class A Stock, par value $0.001 per share, and 160 million shares of Common Stock, par value $0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that Class A Stockholders are entitled to ten votes per share, while Common Stockholders are entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's Board of Directors (the "Board") is authorized to issue up to 30 million shares of preferred stock, in series, with rights, privileges, and qualifications of each series determined by the Board.

In October 2001, the Company completed a private placement of $200.0 million aggregate principal amount of senior subordinated notes, which are convertible into shares of the Company's Common Stock. See Note 10.

In November 2006, the Company completed a public offering of 7.6 million shares of Common Stock at a price of $23.03 per share and received proceeds, after expenses, of $174.6 million.

In September 2003, sanofi-aventis purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for $45.0 million. See Note 11.

In December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for an aggregate cash price of $312.0 million. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with the Company. Under the investor agreement, sanofi-aventis has three demand rights to require the Company to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Company's Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the License and Collaboration Agreement under the Company's antibody collaboration with sanofi-aventis (see Note 11) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept (see Note 11), sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of the Company's Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Sanofi-aventis has also agreed not to dispose of any shares of the Company's Common Stock

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3223

Samsung Bioepis Exhibit 1017, pg. 3223

that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2012, subject to certain limited exceptions. Following December 20, 2012, sanofi-aventis will be permitted to sell shares of the Company's Common Stock (i) in a registered underwritten public offering imdertaken pursuant to the demand registration rights granted to sanofi-aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of the Company's Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or more of the outstanding shares of the Company's Common Stock and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by the Company's Board of Directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of the Company's voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by the Company's Board of Directors or proportionally with the votes cast by the Company's other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of the Company's Class A Stock and Common Stock, and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

10. Commitments and Contingencies

a. Operating Leases

The Company currently leases laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, the Company entered into a new operating lease agreement to lease laboratory and office space that is now under construction and expected to be completed in mid-2009 at the Company's current Tarrytown location, plus retain a portion of the Company's existing space. In October 2007, the Company amended the December 2006 operating lease agreement to increase the amount of new space to be leased. The term of the lease is expected to commence in mid-2008 and will expire approximately 16 years later. Under the new lease the Company also has various options and rights on additional space at the Tarrytown site, and will continue to lease its present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for the Company's retained facilities only. The lease provides for monthly payments over the term of the lease related to the Company's retained facilities, the costs of construction and tenant improvements for the Company's new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, the Company issued a letter of credit in the amount of $1.6 million to its landlord, which is collateralized by a $1.6 million bank certificate of deposit. The certificate of deposit has been classified as restricted cash at December 31, 2007 and 2006 in the accompanying financial statements.

In November 2007, the Company entered into a new operating sublease for additional office space in Tarrytown, New York. The lease expires in September 2009 and contains two renewal options to extend the term of the sublease by three months each.

The Company formerly leased manufacturing, office, and warehouse facilities in Rensselaer, New York under an operating lease agreement. The lease provided for base rent plus additional rental charges for utilities, taxes, and operating expenses, as defined. In June 2007, the Company exercised a purchase option under the lease and, in October 2007, purchased the land and building (see Note 6).

The Company leases certain laboratory and office equipment under operating leases which expire at various times through 2011.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3224

Samsung Bioepis Exhibit 1017, pg. 3224

Based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities to be constructed in Tarrytown, New York, as described above, at December 31, 2007, the estimated future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2008	$ 4,686	$ 429	$ 5,115
2009	9,573	339	9,912
2010	14,453	185	14,638
2011	14,713	13	14,726
2012	14,979		14,979
Thereafter	193,643		193,643
	$ 252,047	$ 966	$ 253,013

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
2007	$ 4,632	$ 363	$ 4,995
2006	4,492	307	4,799
2005	4,606	319	4,925

In addition to its rent expense for various facilities, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of $8.8 million, $8.7 million, and $9.5 million for the years ended December 31, 2007, 2006, and 2005, respectively.

b. Convertible Debt

In October 2001, the Company issued $200.0 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company of $192.7 million, after deducting the initial purchasers' discount and out-of-pocket expenses (collectively, "Deferred Financing Costs"). The Notes bear interest at 5.5% per annum, payable semi-annually, and mature on October 17, 2008. Deferred Financing Costs, which are included in other assets, are amortized as interest expense over the period from the Notes' issuance to stated maturity. The Notes are convertible, at the option of the holder at any time, into shares of the Company's Common Stock at a conversion price of approximately $30.25 per share, subject to adjustment in certain circumstances. Regeneron may also redeem some or all of the Notes at any time if the closing price of the Company's Common Stock has exceeded 140% of the conversion price then in effect for a specified period of time. The fair market value of the Notes fluctuates over time. The estimated fair value of the Notes at December 31, 2007 was approximately $206.1 million.

c. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with related and unrelated companies, scientific collaborators, universities, and consultants. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company, services to be provided, and ownership rights to certain proprietary technology developed under the agreements. Some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.25% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

Certain agreements under which the Company is required to pay fees permit the Company, upon 30 to 90-day written notice, to terminate such agreements. With respect to payments associated with these agreements, the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3225

Samsung Bioepis Exhibit 1017, pg. 3225

Company incurred expenses of $1.0 million, $1.1 million, and $1.0 million for the years ended December 31, 2007, 2006, and 2005, respectively.

In July 2002, Amgen Inc. and Immunex Corporation (now part of Amgen) granted the Company a non-exclusive license to certain patents and patent applications which may be used in the development and commercialization of ARCALYST™(rilonacept; also known as IL-1 Trap). The license followed two other licensing arrangements under which Regeneron obtained a non-exclusive license to patents owned by ZymoGenetics, Inc. and Tularik Inc. for use in connection with the ARCALYST™ program. These license agreements would require the Company to pay royalties based on the net sales of ARCALYST™ if and when it is approved for sale. In total, the royalty rate under these three agreements would be in the mid-single digits.

In December 2003, the Company entered into a non-exclusive license agreement with Cellectis Inc. that granted the Company certain rights in a family of patents relating to homologous recombination. Cellectis now claims that agreements the Company entered into relating to its *VelocImmune* mice with AstraZeneca UK Limited, Astellas Pharma Inc., and sanofi-aventis are outside of the scope of the Company's license from Cellectis. The Company disagrees with Cellectis' position and is in discussions with Cellectis regarding this matter. If the Company is not able to resolve this dispute, Cellectis may commence a lawsuit against the Company and its *VelocImmune* licensees alleging infringement of Cellectis' patents. The Company is unable to estimate the losses or expenses, if any, that may result from the resolution of this matter; however, such losses or expenses could be material.

11. Research and Development Agreements

The Company has entered into various agreements related to its activities to develop and commercialize product candidates and utilize its technology platforms. Amounts earned by the Company in connection with these agreements, which were recognized as contract research and development revenue or other contract income, as applicable, totaled $96.6 million, $51.1 million, and $83.1 million in 2007, 2006, and 2005, respectively. Total Company incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost-sharing of a collaborator's development expenses, where applicable (see Bayer HealthCare below), were $108.2 million, $43.4 million and $42.2 million in 2007, 2006, and 2005, respectively. Significant agreements of this kind are described below.

a. The sanofi-aventis Group

Aflibercept

In September 2003, the Company entered into a collaboration agreement (the "Aventis Agreement") with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.), to jointly develop and commercialize aflibercept. In connection with this agreement, sanofi-aventis made a non-refundable, up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for $45.0 million.

In January 2005, the Company and sanofi-aventis amended the Aventis Agreement to exclude intraocular delivery of aflibercept to the eye ("Intraocular Delivery") from joint development under the agreement, and product rights to aflibercept in Intraocular Delivery reverted to Regeneron. In connection with this amendment, sanofi-aventis made a $25.0 million non-refundable payment to Regeneron (the "Intraocular Termination Payment") in January 2005.

In December 2005, the Company and sanofi-aventis amended the Aventis Agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a $25.0 million non-refundable, up-front payment to the Company, which was received in January 2006. Under the Aventis Agreement, as amended, the Company and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan, for disease indications

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3226

Samsung Bioepis Exhibit 1017, pg. 3226

included in the companies' collaboration. The Company is entitled to a royalty of approximately 35% on annual sales of aflibercept in Japan, subject to certain potential adjustments. The Company may also receive up to $400.0 million in additional milestone payments upon receipt of specified marketing approvals. This total includes up to $360.0 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union. Another $40.0 million of milestone payments relate to receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

Under the Aventis Agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of these development expenses, or half of $306.8 million as of December 31, 2007, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits and Japan royalties, or at a faster rate at Regeneron's option. Regeneron has the option to conduct additional pre-Phase III studies at its own expense. In connection with the January 2005 amendment to the Aventis Agreement, the Intraocular Termination Payment of $25.0 million will be considered an aflibercept development expense and will be subject to 50% reimbursement by Regeneron to sanofi-aventis, as described above, if the collaboration becomes profitable. In addition, if the first commercial sale of an aflibercept product in Intraocular Delivery predates the first commercial sale of an aflibercept product under the collaboration by two years, Regeneron will begin reimbursing sanofi-aventis for up to $7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, Regeneron's obligation to reimburse sanofi-aventis, for 50% of aflibercept development expenses will terminate, and the Company will retain all rights to aflibercept.

Revenue related to payments from sanofi-aventis under the Aventis Agreement, as amended, is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The up-front payments received in September 2003 and January 2006, of $80.0 million and $25.0 million, respectively, and reimbursement of Regeneron-incurred development expenses, are being recognized as contract research and development revenue over the related performance period. The Company recognized $47.1 million, $47.8 million, and $43.4 million of contract research and development revenue in 2007, 2006, and 2005, respectively, in connection with the Aventis Agreement, as amended. The Company also recognized the $25.0 million Intraocular Termination Payment as other contract income in 2005. At December 31, 2007 and 2006, amounts receivable from sanofi-aventis totaled $10.5 million and $6.9 million, respectively, and deferred revenue was $61.2 million and $70.0 million, respectively, in connection with the Aventis Agreement.

Antibodies

In November 2007, the Company entered into a global, strategic collaboration (the "Antibody Collaboration") with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. In connection with the collaboration, in December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for $312.0 million (see Note 9).

The Antibody Collaboration is governed by a Discovery and Preclinical Development Agreement (the "Discovery Agreement") and a License and Collaboration Agreement (the "License Agreement"). The Company received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the Discovery Agreement. In addition, sanofi-aventis will fund up to $475.0 million of the Company's research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against such targets through December 31, 2012, subject to specified funding limits of $75.0 million for the period from the collaboration's inception through December 31, 2008, and $100.0 million annually in each of the next four years. The Discovery

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3227

Samsung Bioepis Exhibit 1017, pg. 3227

Agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the Discovery Agreement, sanofi-aventis has the option to license rights to the candidate under the License Agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with the Company through product approval. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the License Agreement, the Company will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. Upon inception of the Antibody Collaboration, the Company and sanofi-aventis began co-developing the first therapeutic antibody, REGN88, under the License Agreement.

Under the License Agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") will be shared 80% by sanofi-aventis and 20% by Regeneron. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of $0.7 million as of December 31, 2007) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products.

Sanofi-aventis will lead commercialization activities for products developed under the License Agreement, subject to the Company's right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (Regeneron) and ending at 55% (sanofi-aventis)/45% (Regeneron), and losses outside the United States at 55% (sanofi-aventis)/45% (Regeneron). In addition to profit sharing, the Company is entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured.

With respect to each antibody product which enters development under the License Agreement, sanofi-aventis or the Company may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. The Company may also opt-out of the further development of an antibody product if it gives notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the License Agreement. Each of the Discovery Agreement and the License Agreement contains other termination provisions, including for material breach by the other party and, in the case of the Discovery Agreement, a termination right for sanofi-aventis under certain circumstances, including if certain minimal criteria for the discovery program are not achieved. Prior to December 31, 2012, sanofi-aventis has the right to terminate the Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to the Company the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate. Upon expiration of the Discovery Agreement, sanofi-aventis has an option to license the Company's *VelocImmune* technology for agreed upon consideration.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3228

Samsung Bioepis Exhibit 1017, pg. 3228

Revenue related to payments from sanofi-aventis under the Antibody Collaboration is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The $85.0 million up-front payment received in December 2007 and reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements are being recognized as contract research and development revenue over the related performance period. In connection with the Antibody Collaboration, the Company recognized $4.6 million of contract research and development revenue in 2007. In addition, at December 31, 2007, amounts receivable from sanofi-aventis totaled $3.7 million and deferred revenue was $84.1 million.

b. Bayer HealthCare LLC

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer HealthCare made a non-refundable, up-front payment to the Company of $75.0 million. In addition, the Company is eligible to receive up to $110.0 million in development and regulatory milestones related to the VEGF Trap-Eye program, of which the Company received a $20.0 million milestone payment in August 2007 in connection with the initiation of a Phase 3 trial of the VEGF Trap-Eye in the neovascular form of age-related macular degeneration ("wet AMD"). The Company is also eligible to receive up to an additional $135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200.0 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer HealthCare out of its share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of $25.4 million as of December 31, 2007) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. Within the United States, the Company is responsible for any future commercialization of the VEGF Trap-Eye and retains exclusive rights to any future profits from commercialization.

Agreed upon development expenses incurred by both companies in 2007 under a global development plan were shared as follows: The first $50.0 million were shared equally and the Company was solely responsible for up to the next $40.0 million. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

In 2008, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first $70.0 million will be shared equally, the Company is solely responsible for up to the next $30.0 million; and over $100.0 million will be shared equally. In 2009 and thereafter, all development expenses will be shared equally. Regeneron is also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

Bayer HealthCare has the right to terminate the Bayer Agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to the VEGF Trap-Eye.

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue for financial statement purposes. In the fourth quarter of 2007, Regeneron and Bayer HealthCare approved a global development plan for the VEGF Trap-Eye in wet AMD. The plan includes estimated development steps, timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. In addition, in the fourth quarter of 2007, Regeneron and Bayer

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3229

Samsung Bioepis Exhibit 1017, pg. 3229

HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for the VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's VEGF Trap-Eye development expenses, and the financial statement classifications and periods in which past and future payments from Bayer HealthCare (including the $75.0 million up-front payment and development and regulatory milestone payments) and cost-sharing of VEGF Trap-Eye development expenses will be recognized in the Company's Statement of Operations.

The $75.0 million up-front licensing payment and $20.0 million milestone payment (which was not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue over the related estimated performance period in accordance with SAB 104 and EITF 00-21 (see Note 2). In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse. In the fourth quarter of 2007, when the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, the Company recognized, as a cumulative catch-up, contract research and development revenue of $35.9 million, consisting of (i) $15.9 million related to the $75.0 million up-front licensing payment and the $20.0 million milestone payment, and (ii) $20.0 million related to the portion of the Company's 2007 VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In addition, in the fourth quarter of 2007, the Company recognized as additional research and development expense a cumulative catch-up of $10.6 million of 2007 VEGF Trap-Eye development expenses that the Company was obligated to reimburse to Bayer HealthCare.

At December 31, 2007, in connection with cost-sharing of VEGF Trap-Eye development expenses under the collaboration, $4.9 million was payable to Bayer HealthCare and $2.8 million was receivable from Bayer HealthCare. In addition, at December 31, 2007 and 2006, deferred revenue from the Company's collaboration with Bayer HealthCare was $79.1 million and $75.0 million, respectively.

c. The Procter & Gamble Company

In May 1997, the Company entered into a long-term collaboration with The Procter & Gamble Company to discover, develop, and commercialize pharmaceutical products, and Procter & Gamble agreed to provide funding for Regeneron's research efforts related to the collaboration. In accordance with the companies' collaboration agreement (the "P&G Agreement"), Procter & Gamble was obligated to fund Regeneron research on therapeutic areas that were of particular interest to Procter & Gamble through December 2005, with no further research obligations by either party thereafter. Under the P&G Agreement, research support from Procter & Gamble was $2.5 million per quarter, plus adjustments for inflation, through December 2005.

In June 2005, the Company and Procter & Gamble amended the P&G Agreement. Pursuant to the terms of the modified agreement, the Company and Procter & Gamble agreed that the research activities of the parties under the P&G Agreement were completed on June 30, 2005, six months prior to the December 31, 2005 expiration date in the P&G Agreement. In connection with the amendment, Procter & Gamble made a one-time $5.6 million payment to Regeneron and the Company paid approximately $1.0 million to Procter & Gamble to acquire certain capital equipment owned by Procter & Gamble and located at the Company's facilities. Procter & Gamble and the Company divided rights to research programs and pre-clinical product candidates that were developed during the research term of the P&G Agreement. Neither party has the right to participate in the development or commercialization of the other party's product candidates. The Company is entitled to receive royalties based on any future

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3230

Samsung Bioepis Exhibit 1017, pg. 3230

product sales of a Procter & Gamble pre-clinical candidate arising from the collaboration, and Procter & Gamble is entitled to receive a small royalty on any sales of a single Regeneron candidate that is currently not being developed. Neither party is entitled to receive royalties or other payments based on any other products arising from the collaboration.

Contract research and development revenue related to the Company's collaboration with Procter & Gamble was $6.0 million in 2005. In addition, the one-time $5.6 million payment made by Procter & Gamble to the Company in connection with the amendment to the P&G Agreement was recognized as other contract income in 2005.

d. Serono, S.A. (now part of Merck KGaA)

In December 2002, the Company entered into an agreement (the "Serono Agreement") with Serono S.A. to use Regeneron's proprietary *VelociGene®* technology platform to provide Serono with knock-out and transgenic mammalian models of gene function ("Materials"). The Serono Agreement contains provisions for minimum yearly order quantities. In connection with its orders for Materials, Serono makes advance payments to Regeneron, which are accounted for as deferred revenue. Regeneron recognizes revenue and reduces the deferred revenue balance as Materials are shipped to and accepted by Serono. In 2007, 2006, and 2005, the Company recognized $2.4 million, $1.8 million, and $2.2 million, respectively, of contract research and development revenue in connection with the Serono Agreement.

e. National Institutes of Health

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. The NIH grant provides a minimum of $17.9 million in funding over a five-year period, subject to compliance with its terms and annual funding approvals, for the Company's use of its *VelociGene* technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells which can be used to produce knockout mice. The Company will also receive another $1.0 million in funding to optimize certain existing technology for use in the Knockout Mouse Project. In 2007 and 2006, the Company recognized contract research and development revenue of $5.5 million and $0.5 million, respectively, from the NIH Grant.

12. Technology Licensing Agreements

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize the Company's *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million non-refundable, up-front payment to the Company which was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. AstraZeneca is required to make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's *VelocImmune* technology. In connection with the AstraZeneca license agreement, for the year ended December 31, 2007, the Company recognized $17.1 million of revenue and, at December 31, 2007, deferred revenue was $2.9 million.

In March 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million non-refundable, up-front payment to the Company, which was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. Astellas is required to make up to five additional annual payments of

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3231

Samsung Bioepis Exhibit 1017, pg. 3231

$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune* technology. In connection with the Astellas license agreement, for the year ended December 31, 2007, the Company recognized $11.3 million of revenue and, at December 31, 2007, deferred revenue was $8.7 million.

13. Manufacturing Agreement

During 1995, the Company entered into a long-term manufacturing agreement with Merck & Co., Inc., as amended, (the "Merck Agreement") to produce an intermediate (the "Intermediate") for a Merck pediatric vaccine at the Company's Rensselaer, New York facility. The Company modified portions of its facility for manufacture of the Intermediate and assisted Merck in securing regulatory approval for such manufacture in the Company's facility. The Merck Agreement called for the Company to manufacture Intermediate for Merck for a specified period of time (the "Production Period"), with certain minimum order quantities each year. The Production Period commenced in November of 1999 and originally extended for six years. In February 2005, the Company and Merck amended the Merck Agreement to extend the Production Period through October 2006, at which time the Merck Agreement terminated.

Merck agreed to reimburse the Company for the capital costs to modify the facility ("Capital Costs"). Merck also agreed to pay an annual facility fee (the "Facility Fee") of $1.0 million beginning March 1995, subject to annual adjustment for inflation. During the Production Period, Merck agreed to reimburse the Company for certain manufacturing costs, pay the Company a variable fee based on the quantity of Intermediate supplied to Merck, and make additional bi-annual payments ("Additional Payments"), as defined. In addition, Merck agreed to reimburse the Company for the cost of Company activities performed on behalf of Merck prior to the Production Period and for miscellaneous costs during the Production Period ("Internal Costs"). These payments were recognized as contract manufacturing revenue as follows: (i) payments for Internal Costs were recognized as the activities were performed, (ii) the Facility Fee and Additional Payments were recognized over the period to which they related, (iii) payments for Capital Costs were deferred and recognized as Intermediate was shipped to Merck, and (iv) payments related to the manufacture of Intermediate during the Production Period ("Manufacturing Payments") were recognized after the Intermediate was tested and approved by, and shipped (FOB Shipping Point) to, Merck.

In 2006 and 2005, Merck contract manufacturing revenue totaled $12.3 million and $13.7 million, respectively. Such amounts include $1.2 million and $1.4 million of previously deferred Capital Costs, respectively.

14. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan") which, as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3232

Samsung Bioepis Exhibit 1017, pg. 3232

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant. The maximum term of options that have been awarded under the 2000 Incentive Plan is ten years.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the Restricted Stock, which has not vested, will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts, if any, paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

Phantom Stock awards provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of the Company's Common Stock as determined by the Committee, equal to the sum of the fair market value of a share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests. Stock Bonus awards are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Company's Common Stock. Subject to the provisions of the 2000 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

During 1990, the Company established the 1990 Incentive Plan which, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, received awards as determined by a committee of independent directors. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. Awards under the 1990 Incentive Plan consisted of Incentive Stock Options and Nonqualified Stock Options which generally vested on a pro rata basis over a three or five year period and have a term of ten years.

The 1990 and 2000 Incentive Plans contain provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined.

As of December 31, 2007, there were 744,879 shares available for future grants under the 2000 Incentive Plan.

a. Stock Options

Transactions involving stock option awards during 2005, 2006, and 2007 under the 1990 and 2000 Incentive Plans are summarized in the table below.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3233

Samsung Bioepis Exhibit 1017, pg. 3233

Stock Options:	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Intrinsic Value (in thousands)
Outstanding at December 31, 2004	15,140,568	$ 18.68		
2005:				
Granted	4,551,360	$ 10.08		
Forfeited	(1,975,108)	$ 20.83		
Expired	(2,399,410)	$ 30.18		
Exercised	(597,918)	$ 9.50		
Outstanding at December 31, 2005	14,719,492	$ 14.23		
2006:				
Granted	2,742,260	$ 19.59		
Forfeited	(338,122)	$ 10.51		
Expired	(172,218)	$ 24.23		
Exercised	(1,408,907)	$ 9.84		
Outstandiug at December 31, 2006	15,542,505	$ 15.54		
2007:				
Granted	3,415,743	$ 21.78		
Forfeited	(220,342)	$ 14.43		
Expired	(50,759)	$ 13.73		
Exercised	(1,014,791)	$ 10.58		
Outstanding at December 31, 2007	17,672,356	$ 17.05	6.68	$ 146,827
Vested and expected to vest at December 31, 2007	16,945,428	$ 17.09	6.62	$ 140,881
Exercisable at December 31, 2005	7,321,256	$ 17.79		
Exercisable at December 31, 2006	7,890,856	$ 17.41		
Exercisable at December 31, 2007	9,369,665	$ 17.02	5.27	$ 86,252

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2007, 2006, and 2005 was $12.6 million, $13.2 million, and $1.6 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The Company grants stock options with exercise prices that are equal to or greater than the market price of the Company's Common Stock on the date of grant. The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2005, 2006, and 2007.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3234

Samsung Bioepis Exhibit 1017, pg. 3234

	Number of Options Granted	Weighted-Average Exercise Price	Weighted-Average Fair Value
2005:			
Exercise price equal to market price	4,551,360	$ 10.08	$ 6.68
2006:			
Exercise price equal to market price	2,742,260	$ 19.59	$ 12.82
2007:			
Exercise price equal to market price	3,415,743	$ 21.78	$ 11.13

The following table summarizes stock option information as of December 31, 2007:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$ 4.83 to $ 8.50	2,075,472	3.35	$ 8.19	840,272	$ 7.80
$ 8.52 to $ 9.49	2,539,210	5.76	$ 9.30	1,973,719	$ 9.26
$ 9.50 to $11.64	2,122,728	7.79	$ 11.61	1,028,792	$ 11.59
$11.70 to $17.89	2,300,442	6.28	$ 13.47	2,018,882	$ 13.25
$18.17 to $20.32	3,481,247	7.91	$ 19.96	1,496,971	$ 19.73
$20.79 to $27.07	3,221,553	9.72	$ 22.05	79,325	$ 23.50
$27.53 to $37.94	1,871,704	3.45	$ 32.85	1,871,704	$ 32.85
$51.56 to $51.56	60,000	2.16	$ 51.56	60,000	$ 51.56
$ 4.83 to $51.56	17,672,356	6.68	$ 17.05	9,369,665	$ 17.02

Non-cash stock-based employee compensation expense recognized in operating expenses is provided in Note 2. As of December 31, 2007, there was $60.6 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years. In addition, there are 723,092 options which are unvested as of December 31, 2007 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals $2.7 million and will begin to be recognized only if, and when, these options' performance condition is considered to be probable of attainment.

Fair value Assumptions:

The fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Incentive Plan during 2007, 2006, and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The following table summarizes

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3235

Samsung Bioepis Exhibit 1017, pg. 3235

the weighted average values of the assumptions used in computing the fair value of option grants during 2007, 2006, and 2005.

	2007	2006	2005
Expected volatility	53%	67%	71%
Expected lives from grant date	5.6 years	6.5 years	5.9 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	3.60%	4.51%	4.16%

2005 Stock Option Exchange:

In December 2004, the Company's shareholders approved a stock option exchange program. Under the program, Company regular employees who work an average of 20 hours per week, other than the Company's chairman and the Company's president and chief executive officer, were provided the opportunity to make a one-time election to surrender options granted under the 1990 and 2000 Incentive Plans that had an exercise price of at least $18.00 and exchange them for replacement options granted under the 2000 Incentive Plan in accordance with the following exchange ratios:

Exercise Price of Eligible Options	Exchange Ratio (Number of Eligible Options to be Surrendered and Cancelled for Each Replacement Option)
$18.00 to $28.00	1.50
$28.01 to $37.00	2.00
$37.01 and up	3.00

Participation in the stock option exchange program was voluntary, and non-employee directors, consultants, former employees, and retirees were not eligible to participate. The participation deadline was January 5, 2005 and 329 eligible employees participated in the program. These employees elected to exchange options with a total of 3,665,819 underlying shares of Common Stock, and the Company issued 1,977,840 replacement options with an exercise price of $8.50 per share on January 5, 2005.

Each replacement option was completely unvested upon grant. Each replacement option granted to an employee other than our executive vice president and senior vice presidents will ordinarily become vested and exercisable with respect to one-fourth of the shares initially underlying such option on each of the first, second, third and fourth anniversaries of the grant date so that such replacement option will be fully vested and exercisable four years after it was granted. Each replacement option granted to the Company's executive vice president and senior vice presidents will ordinarily vest with respect to all shares underlying such option if both (i) the Company's products have achieved gross sales of at least $100 million during any consecutive twelve month period (either directly by the Company or through its licenses) and (ii) the specific executive or senior vice president has remained employed by the Company for at least three years from the date of grant. For all replacement options, the recipient's vesting and exercise rights are contingent upon the recipients continued employment through the applicable vesting date and subject to the other terms of the 2000 Incentive Plan and the applicable option award agreement. As is generally the case with respect to the option award agreements for options that were eligible for exchange pursuant to the stock option exchange program, the option award agreements for replacement options include provisions whereby the replacement options may be fully vested in connection with a "Change in Control" of the Company, as defined in the 2000 Incentive Plan.

Under the stock option exchange program, each replacement option has a term equal to the greater of (i) the remaining term of the surrendered option it replaces and (ii) six years from the date of grant of the replacement

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3236

Samsung Bioepis Exhibit 1017, pg. 3236

option. This was intended to ensure that the employees who participated in the stock option exchange program would not derive any additional benefit from an extended option term unless the surrendered option had a remaining term of less than six years. In connection with the replacement options issued under the stock option exchange program, the Company will recognize total incremental compensation cost of $2.0 million over the vesting periods of these options.

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the years ended December 31, 2005 and 2006 is summarized below:

Restricted Stock:		Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2004		286,417	$ 12.40
2005:	Forfeited	(4,601)	$ 11.70
	Released	(186,628)	$ 13.05
	Outstanding at December 31, 2005	95,188	$ 11.16
2006:	Forfeited	(1,703)	$ 9.74
	Released	(93,485)	$ 11.18
	Outstanding at December 31, 2006	—	
2007:	Granted	500,000	$ 21.92
	Outstanding at December 31, 2007	500,000	$ 21.92

In December 2007, the Company awarded a grant of Restricted Stock to the Company's executive vice president. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to grants of Restricted Stock awards. This amount is based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restriction on these shares lapse, which is five years for the grant made in 2007, approximately two years for grants made in 2003, and 18 months for grants made in 2004. In addition, unearned compensation in Stockholders' Equity is reduced due to forfeitures of Restricted Stock resulting from employee terminations. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation is combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

In connection with the 2007 grant of Restricted Stock, the Company recorded unearned compensation in Stockholder's Equity of $11.0 million, which was combined with additional paid-in capital. In connection with forfeitures of past Restricted Stock awards, the Company reduced unearned compensation by $17 thousand and $0.1 million in 2006 and 2005, respectively. The Company recognized non-cash compensation expense from Restricted Stock awards of $0.1 million, $0.3 million, and $1.9 million in 2007, 2006, and 2005, respectively. As of December 31, 2007, there were 500,000 unvested shares of Restricted Stock outstanding and $10.9 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses.

15. Executive Stock Purchase Plan

In 1989, the Company adopted an Executive Stock Purchase Plan (the "Plan") under which 1,027,500 shares of Class A Stock were reserved for restricted stock awards. The Plan provides for the compensation committee of the board of directors to award employees, directors, consultants, and other individuals ("Plan participants") who render service to the Company the right to purchase Class A Stock at a price set by the compensation committee. The Plan provides for the vesting of shares as determined by the compensation committee and, should the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3237

Samsung Bioepis Exhibit 1017, pg. 3237

Company's relationship with a Plan participant terminate before all shares are vested, unvested shares will be repurchased by the Company at a price per share equal to the original amount paid by the Plan participant. During 1989 and 1990, a total of 983,254 shares were issued, all of which vested as of December 31, 1999. As of December 31, 2007, there were 44,246 shares available for future grants under the Plan.

16. Employee Savings Plan

In 1993, the Company adopted the provisions of the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan provide for employees who have met defined service requirements to participate in the Savings Plan by electing to contribute to the Savings Plan a percentage of their compensation to be set aside to pay their future retirement benefits, as defined. The Savings Plan, as amended and restated, provides for the Company to make discretionary contributions ("Contribution"), as defined. The Company recorded Contribution expense of $1.4 million in 2007, $1.3 million in 2006, and $2.0 million in 2005; such amounts were accrued as liabilities at December 31, 2007, 2006, and 2005, respectively. During the first quarter of 2008, 2007, and 2006, the Company contributed 58,575, 64,532, and 120,960 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

17. Income Taxes

In 2007, 2006, and 2005, the Company incurred net losses for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes has been recorded in the accompanying financial statements.

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2007 and 2006 was as follows:

	2007	2006
Deferred tax assets:		
Net operating loss carry-forward	$ 166,714	$ 177,034
Fixed assets	17,245	15,640
Deferred revenue	96,148	58,739
Deferred compensation	15,159	14,213
Research and experimental tax credit carry-forward	25,446	23,248
Capitalized research and development costs	15,236	19,555
Other	7,036	3,897
Valuation allowance	(342,984)	(312,326)
	—	—

The Company's valuation allowance increased by $30.7 million in 2007, due primarily to the temporary difference related to deferred revenue, principally resulting from the non-refundable up-front payment received from sanofi-aventis in December 2007 (see Note 11). In 2006, the Company's valuation allowance increased by $41.6 million, due primarily to increases in the Company's net operating loss carry-forward and the temporary difference related to deferred revenue, principally resulting from the non-refundable up-front payment received from Bayer HealthCare in 2006 (see Note 11).

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*. The implementation of FIN 48 had no impact on the Company's financial statements as the Company has not recognized any uncertain income tax positions.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3238

Samsung Bioepis Exhibit 1017, pg. 3238

The Company is primarily subject to U.S. federal and New York State income tax. For all years presented, the Company's effective income tax rate is zero. The difference between the Company's effective income tax rate and the Federal statutory rate of 35% is attributable to state tax benefits and tax credit carry-forwards offset by an increase in the deferred tax valuation allowance. The Company's 1992 and subsequent tax years remain open to examination by U.S. federal and state tax authorities.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of January 1 and December 31, 2007, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2007, the Company had available for tax purposes unused net operating loss carry-forwards of $423.2 million which will expire in various years from 2008 to 2027 and included $12.7 million of net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of Incentive Stock Options, the tax benefit from which, if realized, will be credited to additional paid-in capital. The Company's research and experimental tax credit carry-forwards expire in various years from 2008 to 2027. Under the Internal Revenue Code and similar state provisions, substantial changes in the Company's ownership have resulted in an annual limitation on the amount of net operating loss and tax credit carry-forwards that can be utilized in future years to offset future taxable income. This annual limitation may result in the expiration of net operating losses and tax credit carry-forwards before utilization.

18. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition. Costs associated with the Company's resolution of legal proceedings are expensed as incurred.

19. Net Loss Per Share Data

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. In 2007, 2006, and 2005, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	December 31,		
	2007	2006	2005
Net loss (Numerator)	$ (105,600)	$ (102,337)	$ (95,446)
Weighted-average shares, in thousands (Denominator)	66,334	57,970	55,950
Basic and diluted net loss per share	$ (1.59)	$ (1.77)	$ (1.71)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3239

Samsung Bioepis Exhibit 1017, pg. 3239

Shares issuable upon the exercise of options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the diluted per share amounts because their effect would have been antidilutive, include the following:

	December 31,		
	2007	2006	2005
Options:			
Weighted average number, in thousands	15,385	14,139	13,299
Weighted average exercise price	$ 15.97	$ 14.41	$ 14.59
Restricted Stock:			
Weighted average number, in thousands	21	23	165
Convertible Debt:			
Weighted average number, in thousands	6,611	6,611	6,611
Conversion price	$ 30.25	$ 30.25	$ 30.25

In connection with the Company's stock option exchange program (see Note 14), on January 5, 2005, eligible employees elected to exchange options with a total of 3,665,819 underlying shares of Common Stock, and the Company issued 1,997,840 replacement options with an exercise price of $8.50 per share.

20. Segment Information

Through 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. This segment includes revenues and expenses related to activities conducted under research and development agreements (see Note 11) and technology licensing agreements (see Note 12).

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006 and 2005, the Company produced a vaccine intermediate for Merck & Co., Inc. under a manufacturing agreement, which expired in October 2006 (see Note 13).

The accounting policies for the segments are the same as those described in Note 2, Summary of Significant Accounting Policies. Due to the expiration of the Company's manufacturing agreement with Merck in October 2006, beginning in 2007, the Company only has a research and development business segment. Therefore, segment information has not been provided for 2007 in the table below.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3240

Samsung Bioepis Exhibit 1017, pg. 3240

The following table presents information about reported segments for the years ended December 31, 2006 and 2005.

	Research & Development	Contract Manufacturing	Reconciling Items	Total
2006				
Revenues	$ 51,136	$ 12,311	—	$ 63,447
Depreciation and amortization	13,549	—(1)	$ 1,043	14,592
Non-cash compensation expense	18,357	318	(813)(2)	17,862
Interest expense	—	—	12,043	12,043
Net income (loss)	(111,820)	4,165	5,318(3)	(102,337)
Capital expenditures	3,339	—	—	3,339
Total assets	56,843	3	528,244(4)	585,090
2005				
Revenues	$ 52,447	$ 13,746	—	$ 66,193
Depreciation and amortization	14,461	—(1)	$ 1,043	15,504
Non-cash compensation expense	21,492	367	—	21,859
Interest expense	—	—	12,046	12,046
Other contract income	30,640	—	—	30,640
Net income (loss)	(97,970)	4,189	(1,665)(3)	(95,446)
Capital expenditures	4,667	—	—	4,667
Total assets	95,645	4,315	323,541(4)	423,501

(1) Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

(2) Represents the cumulative effect of adopting SFAS 123R (see Note 2).

(3) Represents investment income net of interest expense related to convertible notes issued in October 2001 (see Note 10). For the year ended December 31, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 2).

(4) Includes cash and cash equivalents, marketable securities, restricted cash (where applicable), prepaid expenses and other current assets, and other assets.

21. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2007 and 2006 are set forth in the following tables.

	First Quarter Ended March 31, 2007	Second Quarter Ended June 30, 2007	Third Quarter Ended September 30, 2007	Fourth Quarter Ended December 31, 2007 (1)
		(Unaudited)		
Revenues	$ 15,788	$ 22,195	$ 22,311	$ 64,730
Net loss	(29,917)	(26,774)	(35,838)	(13,071)
Net loss per share, basic and diluted	$ (0.46)	$ (0.41)	$ (0.54)	$ (0.19)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3241

Samsung Bioepis Exhibit 1017, pg. 3241

	First Quarter Ended March 31, 2006	Second Quarter Ended June 30, 2006	Third Quarter Ended September 30, 2006	Fourth Quarter Ended December 31, 2006
	(Unaudited)			
Revenues	$ 18,219	$ 19,258	$ 15,624	$ 10,346
Net loss before cumulative effect of a change in accounting principle	(21,193)	(23,576)	(27,410)	(30,971)
Net loss	(20,380)	(23,576)	(27,410)	(30,971)
Net loss per share, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	$ (0.37)	$ (0.41)	$ (0.48)	$ (0.51)
Net loss	$ (0.36)	$ (0.41)	$ (0.48)	$ (0.51)

(1) As described in Note 11, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. As a result, in the fourth quarter of 2007, when the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, the Company recognized contract research and development revenue from Bayer HealthCare of $35.9 million and additional research and development expense of $10.6 million.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3242

Samsung Bioepis Exhibit 1017, pg. 3242

EXHIBIT INDEX

Exhibit Number		Description
3.1		— Restated Certificate of Incorporation, filed February 11, 2008 with the New York Secretary of State.
3.2	(a)	— By-Laws of the Company, currently in effect (amended through November 9, 2007).
10.1	(b)	— 1990 Amended and Restated Long-Term Incentive Plan.
10.2	(c)	— 2000 Long-Term Incentive Plan.
10.3.1	(d)	— Amendment No. 1 to 2000 Long-Term Incentive Plan, effective as of June 14, 2002.
10.3.2	(d)	— Amendment No. 2 to 2000 Long-Term Incentive Plan, effective as of December 20, 2002.
10.3.3	(e)	— Amendment No. 3 to 2000 Long-term Incentive Plan, effective as of June 14, 2004.
10.3.4	(f)	— Amendment No. 4 to 2000 Long-term Incentive Plan, effective as of November 15, 2004.
10.3.5	(g)	— Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10.3.6	(g)	— Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.3.7	(h)	— Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.4	(d)	— Employment Agreement, dated as of December 20, 2002, between the Company and Leonard S. Schleifer, M.D., Ph.D.
10.5*	(i)	— Employment Agreement, dated as of December 31, 1998, between the Company and P. Roy Vagelos, M.D.
10.6	(j)	— Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, effective as of February 1, 2006.
10.7	(k)	— Indenture, dated as of October 17, 2001, between Regeneron Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, as trustee.
10.8	(k)	— Registration Rights Agreement, dated as of October 17, 2001, among Regeneron Pharmaceuticals, Inc., Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Robertson Stephens, Inc.
10.9*	(l)	— IL-1 License Agreement, dated June 26, 2002, by and among the Company, Immunex Corporation, and Amgen Inc.
10.10*	(m)	— Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
10.11*	(n)	— Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.11.1*	(i)	— Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 31, 2004.
10.11.2	(o)	— Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of January 7, 2005.
10.11.3*	(p)	— Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 21, 2005.
10.11.4*	(p)	— Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals, Inc.) and Regeneron Pharmaceuticals, Inc., effective as of January 31, 2006.
10.12	(n)	— Stock Purchase Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.13*	(q)	— License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
10.14*	(r)	— Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007 by and between AstraZeneca UK Limited and Regeneron Pharmaceuticals, Inc.

Exhibit Number	Description	
10.15	(s)	— Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc.
10.16*	(t)	— Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
10.17*	(u)	— First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
10.18*		— Discovery and Preclinical Development Agreement, dated as of November 28, 2007, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.19*		— License and Collaboration Agreement, dated as of November 28, 2007, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord and Regeneron Pharmaceuticals, Inc.
10.20		— Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.
10.21		— Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and Regeneron Pharmaceuticals, Inc.
12.1		— Statement re: computation of ratio of earnings to combined fixed charges of Regeneron Pharmaceuticals, Inc.
23.1		— Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1		— Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2		— Certification of CFO pursuant to Rule 13a-14 (a) under the Securities and Exchange Act of 1934.
32		— Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

(a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.

(b) Incorporated by reference from the Company's registration statement on Form S-1 (file number 33-39043).

(c) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2001, filed March 22, 2002.

(d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2002, filed March 31, 2003.

(e) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2004, filed August 5, 2004.

(f) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 17, 2004.

(g) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.

(h) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.

(i) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2004, filed March 11, 2005.

(j) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 25, 2006.

(k) Incorporated by reference from the Company's registration statement on Form S-3 (file number 333-74464).

(l) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.

(m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.

(n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 11, 2003.

(o) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.

(p) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2005, filed February 28, 2006.

(q) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed October 18, 2006.
(r) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2006, filed March 12, 2007.
(s) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
(t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended March 31, 2007, filed May 4, 2007.
(u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended September 31, 2007, filed November 7, 2007.
* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

Exhibit 3.1

RESTATED CERTIFICATE OF INCORPORATION

OF REGENERON PHARMACEUTICALS, INC.

UNDER SECTION 807 THE BUSINESS CORPORATION LAW

The undersigned hereby certify that:

1. The name of the Corporation is Regeneron Pharmaceuticals, Inc. (the "Corporation").

2. The Certificate of Incorporation of the Corporation was filed with the Department of State of the State of New York on January 11, 1988.

3. This Restated Certificate of Incorporation restates the Certificate of Incorporation, as heretofore amended, without amendment or change to read as herein set forth in full.

4. This Restated Certificate of Incorporation has been authorized by resolution duly adopted by the Corporation's Board of Directors.

Accordingly, the Certificate of Incorporation, as heretofore amended, is hereby restated to be and read in its entirety as follows:

"ARTICLE I

NAME OF CORPORATION

The name of the corporation is Regeneron Pharmaceuticals, Inc. (the "Corporation").

ARTICLE II

CORPORATE PURPOSES

The purpose or purposes for which the Corporation is formed is as follows, to wit:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3246

Samsung Bioepis Exhibit 1017, pg. 3246

To own, operate, manage and do everything normally associated with conducting the business of chemists, druggists, manufacturers, researchers, distributors, and dealers in medical, pharmaceutical, chemical and other preparations and compounds.

To engage in any lawful act or activity for which corporations may be formed under the Business Corporation Law. The Corporation is not formed to engage in any act or activity requiring the consent or approval of any state official, department, board, agency or other body without such consent or approval first being obtained.

To own, operate, manage, acquire and deal in property, real and personal, which may be necessary to the conduct of the business.

The Corporation shall have all of the powers enumerated in Section 202 of the Business Corporation Law, subject to any limitations provided in the Business Corporation Law or any other statutes in the State of New York.

ARTICLE III

COUNTY OF OFFICE

The county in which the office of the Corporation is to be located in the State of New York is New York.

ARTICLE IV

STOCK

The aggregate number of shares of all classes of capital stock which the Corporation shall have the authority to issue is two hundred and thirty million (230,000,000) shares, consisting of (a) 160,000,000 shares of common stock, par value $.001 per share ("Common Stock"), (b) 40,000,000 shares of Class A Stock, par value $.001 per share (the "Class A Stock", and collectively, such Common Stock and Class A Stock are referred to herein as the "Common Shares"), and (c) 30,000,000 shares of preferred stock, par value $.01 per share.

1. Preferred Stock

The Board of Directors is hereby expressly authorized, by resolution or resolutions, to provide, out of the unissued and undesignated shares of preferred stock, for one or more series of preferred stock. Before any shares of any such series are issued, the Board of Directors shall fix, and hereby is expressly empowered to fix, by resolution or resolutions, the following provisions of the shares thereof:

(a) the designation of such series, the number of shares to constitute such series, and the stated value thereof if different from the par value thereof;

(b) whether the shares of such series shall have voting rights, in addition to any voting rights provided by law, and, if so, the terms of such voting rights, which may be general or limited;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3247

Samsung Bioepis Exhibit 1017, pg. 3247

(c) the dividends, if any, payable on such series, whether any such dividends shall be cumulative, and, if so, from what dates, the conditions and dates upon which such dividends shall be payable, the preference or relation which such dividends shall bear to the dividends payable on any shares of stock of any other class or any other series of this class;

(d) whether the shares of such series shall be subject to redemption by the Corporation, and, if so, the terms and conditions of such redemption, including the manner of selecting shares for redemption if less than all shares of such series are to be redeemed, the date or dates upon or after which they shall be redeemable, and the amount per share payable in case of redemption, which amount may vary under different conditions and at different redemption dates;

(e) the amount or amounts payable upon shares of such series upon, and the rights of the holders of such series in, the voluntary or involuntary liquidation, dissolution or winding up, or upon any distribution of the assets, of the Corporation, and whether such rights shall be in preference to, or in another relation to, the comparable rights of any other class or classes or series of stock;

(f) whether the shares of such series shall be subject to the operation of a retirement or sinking fund and, if so, the extent to and manner in which any such retirement or sinking fund shall be applied to the purchase or redemption of the shares of such series for retirement or other corporate purposes and the terms and provisions relative to the operation thereof;

(g) whether the shares of such series shall be convertible into, or exchangeable for, shares of stock of any other series of this class or any other securities and, if so, the price or prices or the rate or rates of conversion or exchange and the method, if any, of adjusting the same, and any other terms and conditions of conversion or exchange;

(h) the limitations and restrictions, if any, to be effective while any shares of such series are outstanding upon the payments of dividends or the making of other distributions on, and upon the purchase, redemption or other acquisition by the Corporation of, the Common Stock or shares of stock of any other class or any other series of this class;

(i) the conditions or restrictions, if any, upon the creation of indebtedness of the Corporation or upon the issue of any additional stock, including additional shares of such series or of any other series of this class or of any other class; and

(j) any other powers, preferences and relative, participating, optional and other special rights, and any qualifications, limitations and restrictions thereof.

The powers, preferences and relative, participating, optional and other special rights of each series of preferred stock, and the qualifications, limitations of restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. All shares of any one series of preferred stock shall be identical in all respects with all other shares of such series, except that shares of any one series issued at different times may differ as to the dates from which dividends thereon shall accrue and/or be cumulative.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3248

Samsung Bioepis Exhibit 1017, pg. 3248

2. Common Stock and Class A Stock

(a) General. Except as hereinafter expressly set forth in Section 2, and subject to the rights of the holders of preferred stock at any time outstanding, the Class A Stock and the Common Stock, both of which are classes of common stock, shall have the same rights and privileges and shall rank equally, share ratably and be identical in respects as to all matters, including rights in liquidation.

(b) Voting Rights. Except as otherwise expressly provided by law, and subject to any voting rights provided to holders of preferred stock by this Certificate of Incorporation the Common Shares have exclusive voting rights on all matters requiring a vote of shareholders.

The holders of Common Stock shall be entitled to one vote per share on all matters to be voted on by the shareholders of the Corporation. The holders of Class A Stock shall be entitled to ten votes per share on all matters to be voted on by the shareholders of the Corporation.

Except as otherwise provided in this Certificate of Incorporation or as required by law, the holders of shares of Class A Stock and the holders of shares of Common Stock shall vote together as one class on all matters submitted to a vote of shareholders of the Corporation.

(c) Dividends and Distributions. Subject to the rights of the holders of preferred stock, and subject to any other provisions of this Certificate of Incorporation, as it may be amended from time to time, holders of Class A Stock and Common Stock shall be entitled to receive such dividends and other distributions in cash, in property or in shares of the Corporation as may be declared thereon by the Board of Directors from time to time out of assets or funds of the Corporation legally available therefore; provided, however, that no cash, property or share dividend or distribution may be declared or paid on the outstanding shares of either the Class A Stock or the Common Stock unless an identical per share dividend or distribution is simultaneously declared and paid on the outstanding shares of the other such class of common stock; provided, further, however, that a dividend of shares may be declared and paid in Class A Stock to holders of Class A Stock and in Common Stock to holders of Common Stock if the number of shares paid per share to holders of Class A Stock and to holders of Common Stock shall be the same. If the Corporation shall in any manner subdivide, combine or reclassify the outstanding shares of Class A Stock or Common Stock, the outstanding shares of the other such class of common stock shall be subdivided, combined or reclassified proportionally in the same manner and on the same basis as the outstanding shares of Class A Stock or Common Stock, as the case may be, have been subdivided, combined or reclassified.

(d) Optional Conversion.

(1) The shares of Common Stock are not convertible into or exchangeable for shares of Class A Stock or any other shares of securities of the Corporation.

(2) Each share of Class A Stock may be converted, at any time and at the option of the holder thereof, into one fully paid and nonassessable share of Common Stock.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3249

Samsung Bioepis Exhibit 1017, pg. 3249

(e) Mandatory Conversion.

(1) Upon a Transfer by a Holder, other than to a "Permitted Transferee" of such Holder, shares of Class A Stock so Transferred shall, at midnight on the thirtieth day after delivery of written notice by the Corporation to such Holder that such Transfer has been made to a person other than a Permitted Transferee (for purposes of this paragraph (1), the "Conversion Time"), be automatically converted, without further act on anyone's part, into an equal number of shares of Common Stock, and the stock certificates formerly representing such shares of Class A Stock shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of Class A Stock shall not occur if such shares of Class A Stock, prior to the Conversion Time, are Transferred back to such Holder or to one or more Permitted Transferees of such Holder.

(2) For purposes of this Section 2(e): A "Permitted Transferee" of a Holder shall mean, the following:

(i) In the case of any Holder, the Corporation or any one or more of its directly or indirectly wholly owned subsidiaries;

(ii) In the case of a Holder who is a natural person:

(A) The spouse of such Holder (the "Spouse"), any lineal ancestor of such Holder or of the Spouse, and any person who is a lineal descendent of a grandparent of such Holder or of the Spouse, or a spouse of any such lineal descendent or such lineal ancestor (collectively, the "Family Members");

(B) A trust (including a voting trust) exclusively for the benefit of one or more of (x) such Holder, (y) one or more of his or her Family Members or (z) any organization to which contributions are deductible under 501(c)(3) of the Internal Revenue Code of 1986, as amended or any successor provision (the "Internal Revenue Code") or for estate or gift tax purposes (a "Charitable Organization"); provided that such trust may include a general or special power of appointment for such Holder or Family Members (a "Trust"); provided, further, that if by reason of any change in the beneficiaries of such Trust, such Trust would not have qualified, at the time of the Transfer of Class A Stock to such Trust (for purposes of this sub-paragraph (B), the "Transfer Date"), as a Permitted Transferee, all shares of Class A Stock so Transferred to such Trust shall, at midnight on the thirtieth day after delivery of written notice by the Corporation to the trustee of such Trust of such change of beneficiary (for purposes of this sub-paragraph (B), the "Conversion Time"), be automatically converted, without further act on anyone's part, into an equal number of shares of Common stock, and the stock certificates formerly representing such shares of Class A Stock

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3250

Samsung Bioepis Exhibit 1017, pg. 3250

shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of such shares of Class A Stock shall not occur if, prior to the Conversion Time, (x) by reason of additional changes in the beneficiary of such Trust, such Trust would again have qualified as a "Permitted Transferee" of such Holder on the Transfer Date, or (y) such Trust Transfers such shares of Class A Stock to one or more persons who would qualify as a Permitted Transferee of the Holder who Transferred such shares to such Trust as if such Holder did not so Transfer such shares;

(C) A Charitable Organization established solely by one or more of such Holder or a Family Member;

(D) An Individual Retirement Account, as defined in Section 408(a) of the Internal Revenue Code, of which such Holder is a participant or beneficiary, provided that such Holder has the power to direct the investment of funds deposited into such Individual Retirement Account and to control the voting of securities held by such Individual Retirement Account (an "IRA");

(E) A pension, profit sharing, stock bonus or other type of plan or trust of which such Holder is a participant or beneficiary and which satisfies the requirements for qualification under Section 401(k) of the Internal Revenue Code, provided that such Holder has the power to direct the investment of funds deposited into such plan or trust and to control the voting of securities held by such plan or trust (a "Plan");

(F) Any corporation or partnership directly or indirectly controlled, individually or as a group, only by such Holder and/or any of his Permitted Transferees as determined under this clause (ii); provided that if by reason of any change in the direct or indirect control of such corporation or partnership, such corporation or partnership would not have qualified, at the time of the Transfer of Class A Stock to such corporation or partnership, as a Permitted Transferee of such Holder, all shares of Class A Stock so Transferred to such corporation or partnership shall in the manner set forth in paragraph (d) hereof, be converted into an equal number of shares of Common Stock; and

(G) The estate, executor, executrix or other personal representative, custodian, administrator or guardian of such Holder.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3251

Samsung Bioepis Exhibit 1017, pg. 3251

(iii) In the case of a Holder holding the shares of Class A Stock in question as trustee of an IRA, a Plan or a Trust, "Permitted Transferee" means (x) the person who transferred Class A Stock to such IRA, such Plan or such Trust, (y) any Permitted Transferee of any such person determined pursuant to this Section 2(e) and (z) any successor trustee or trustees in such capacity of such IRA, such Plan or such Trust,

(iv) In the case of a Holder which is a partnership, "Permitted Transferee" means any other person, directly or indirectly controlling, controlled by or under direct or indirect common control with such partnership, provided that, if by reason of any change in the direct or indirect control of such person, such person would not have qualified, at the time of the Transfer of the Class A Stock to such person, as a Permitted Transferee of such partnership, all shares of Class A Stock so Transferred to such person shall, in the manner set forth in paragraph (4) hereof, be converted into an equal number of shares of Common Stock;

(v) In the case of a Holder which is a corporation (other than a Charitable Organization) "Permitted Transferee" means any other person directly or indirectly controlling, controlled by or under direct or indirect common control with such corporation; provided that if by reason of any change in the direct or indirect control of such person, such person would not have qualified, at the time of the Transfer of the Class A Stock to such person, as a Permitted Transferee of such corporation, all shares of Class A Stock so Transferred to such person shall, in the manner set forth in paragraph (4) hereof, be converted into an equal number of shares of Common Stock; and

(vi) In the case of a Holder which is the estate of a deceased Holder or who is the executor, executrix or other personal representative, custodian or administrator of such Holder, or guardian of a disabled or adjudicated incompetent Holder or which is the estate of a bankrupt or insolvent Holder, which owns the shares of Class A Stock in question, "Permitted Transferee" means a Permitted Transferee of such deceased, or adjudicated incompetent, disabled, bankrupt or insolvent Holder as otherwise determined pursuant to this Section 2(e).

As used in this Section 2(e), the term "control" means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of the controlled person or entity.

As used in this Section 2(e), the term "Holder" means any holder of Class A Stock or of the proxy to vote shares of Class A Stock.

As used in this Section 2(e), the term "person" shall mean both natural persons and legal entities, unless otherwise specified. The relationship of any person that is derived by or through legal adoption shall be considered a natural relationship.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3252

Samsung Bioepis Exhibit 1017, pg. 3252

Each joint owner of shares or owner of a community property interest in shares of Class A Stock shall be considered a "Holder" of such shares. A minor for whom shares of Class A Stock are held pursuant to a Uniform Transfer to Minors Act or similar law shall be considered a Holder of such shares.

As used in this Section 2(e), a "Transfer" shall mean any Type of transfer of shares of Class A Stock, whether by sale, exchange, gift, operation of law, pledge, or otherwise or any transfer of the power to vote such shares by proxy or by transferring any proxy, and shares of Class A Stock shall refer to either (i) such shares of Class A Stock so transferred, (ii) the power to vote such shares so transferred or (iii) shares of Class A Stock for which the power to vote was so transferred, as the case may be.

(3) Notwithstanding anything to the contrary set forth herein, any Holder may pledge the shares of Class A Stock belonging to such Holder to a pledgee pursuant to a bona fide pledge of such shares as collateral security for indebtedness due to the pledgee, provided that such pledgee does not have the power to vote such shares and such shares remain subject to the provisions of this Section. In the event of foreclosure or other similar action by the pledgee, such shares, at midnight on the thirtieth day after delivery of notice by the Corporation to the pledgor of such foreclosure or other similar action (for purposes of this paragraph (3) the "Conversion Time"), shall be automatically converted, without further act on anyone's part, into an equal number of shares of Common Stock and the stock certificates formerly representing such shares of Class A Stock shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of such shares of Class A Stock shall not occur if, prior to the Conversion Time, (x) such pledged shares of Class A Stock are transferred to a Permitted Transferee of the pledgor or (y) such foreclosure or other similar action is cancelled or annulled so that the pledgor retains the right to vote such shares.

(4) If by reason of any change of the direct or indirect control of a person subsequent to any Transfer to such person, such person would not have qualified, at the time of the Transfer of the Class A Stock to such person (the "Transfer Date"), as a Permitted Transferee under clause (ii)(F), clause (iv) or clause (v), as the case may be, all shares of Class A Stock Transferred pursuant to the relevant clause to such person shall, at midnight on the thirtieth day after delivery of written notice by the Corporation to such person of such change of the direct or indirect control of such person (the "Conversion Time"), be automatically converted, without further act on anyone's part, into an equal number of shares of Common Stock, and the stock certificates formerly representing such shares of Class A Stock shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of Class A Stock shall not occur if, prior to the Conversion Time, (x) by reason of additional changes in the direct or indirect control of such person, such person would again have qualified on the Transfer Date as a "Permitted Transferee" under clause (ii)(F), clause (iv) or clause (v), as the case may be, or (y) such person Transfers all such shares of Class A Stock owned by such person to one or more persons who would qualify as a "Permitted Transferee" of the transferor of the Class A Stock to such person as if the transferor did not Transfer such shares on the Transfer Date.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3253

Samsung Bioepis Exhibit 1017, pg. 3253

(5) A good faith determination by the Board of Directors of the Corporation (x) that a transferee of shares of Class A Stock is or is not a Permitted Transferee of the transferor of such shares to such transferee on the date of Transfer, or (y) that, by reason of any change in the direct or indirect control of such transferee subsequent to such Transfer, such person would have or have not qualified at the time of the Transfer of the Class A Stock to such person as a Permitted Transferee shall be conclusive.

(6) All notices provided for herein shall be deemed to have been delivered three days after being sent by registered or certified mail, return receipt requested, postage prepaid, to the person to whom it is directed. If notice is to a Holder, such notice should be sent to him at the address set forth at the office of the Transfer Agent of the Corporation. If notice is to any other person, such notice should be sent to him at the address known by the Corporation at the time the notice is sent.

(7) The Corporation may, as a condition to the transfer or the registration of transfer of shares of Class A Stock to a purported Permitted Transferee, require the furnishing of such affidavits or other proof as it deems necessary to establish that such transferee is a Permitted Transferee. Each certificate representing shares of Class A Stock shall be endorsed with a legend that states that shares of Class A Stock are not transferable other than to certain transferees and are subject to certain restrictions as set forth in the Certificate of Incorporation of the Corporation filed with the Secretary of the State of New York.

(8) This Section 2(e) may not be amended without the affirmative vote of holders of the majority of the shares of Class A Stock and the affirmative vote of the holders of two-thirds of the shares of Common Stock, each voting separately as a class.

(f) Conversion Procedures.

(1) Each conversion of shares pursuant to Section 2(d) hereto will be effected by the surrender of the certificate or certificates, duly endorsed, representing the shares to be converted at the principal office of the Corporation at any time during normal business hours, together with a written notice by the holder stating the number of shares that such holder desires to convert and the names or name in which he wishes the certificate or certificates for the Common Stock to be issued. Such conversion shall be deemed to have been effected as of the close of business on the date on which such certificate or certificates have been surrendered, and at such time, the rights of any such holder with respect to the converted shares of such holder will cease and the person or persons in whose name or names the certificate or certificates for shares are to be issued upon such conversion will be deemed to have become the holder or holders of record of such shares represented thereby.

Promptly after such surrender, the Corporation will issue and deliver in accordance with the surrendering holder's instructions the certificate or certificates for the Common Stock issuable upon such conversion and a certificate representing any Class A Stock which was represented by the certificate or certificates delivered to the Corporation in connection with such conversion, but which was not converted.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3254

Samsung Bioepis Exhibit 1017, pg. 3254

(2) The issuance of certificates upon conversion of shares pursuant to Section 2(d) hereto will be made without charge to the holder or holders of such shares for any issuance tax (except stock transfer tax) in respect thereof or other costs incurred by the Corporation in connection therewith.

(3) The Corporation shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock or its treasury shares, solely for the purpose of issuance upon the conversion of the Class A Stock, such number of shares of Common Stock as may be issued upon conversion, of all outstanding Class A Stock.

(4) Shares of the Class A Stock surrendered for conversion as above provided or otherwise acquired by the corporation shall be cancelled according to law and shall not be reissued.

ARTICLE V

DESIGNATION OF SECRETARY OF STATE
AS AGENT FOR SERVICE OF PROCESS

The Secretary of State is designated as agent of the Corporation upon whom process against it may be served. The post office address to which the Secretary of State shall mail a copy of any process against the Corporation served upon him is:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591

Attention: Secretary

ARTICLE VI

BOARD OF DIRECTORS

The number of Directors of the Corporation constituting the entire Board of Directors shall be not less than three or more than fifteen. The Board of Directors shall determine from time to time the number of Directors who shall constitute the entire Board of Directors. Any such determination made by the Board of Directors shall continue in effect unless and until changed by the Board of Directors, but no such change shall affect the term of any Directors then in office. Directors need not be shareholders of the Corporation.

Commencing at the Annual Meeting of Shareholders held in 1991, the terms of office of the Board of Directors shall be divided into three classes, Class I, Class II and Class III, as shall be determined by the Board of Directors. All classes shall be as nearly equal in number as possible, and no class shall include less than three nor more than nine Directors. Any vacancy on the Board of Directors that results from an increase in the number of Directors and any other vacancy on the Board may be filled only by the Board provided that a quorum is then in office and present, or only by a majority of the Directors then in office, if less than a quorum is then in

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3255

Samsung Bioepis Exhibit 1017, pg. 3255

office, or by a sole remaining Director. Directors elected to fill a newly created directorship or other vacancies shall be classified and hold office as provided by statute.

The terms of office of the respective classes of directors initially classified shall be as follows: (1) Class I shall expire at the Annual Meeting of Shareholders to be held in 1992; (2) Class II shall expire at the Annual Meeting of Shareholders to be held in 1993; and (3) Class III shall expire at the Annual Meeting of Shareholders to be held in 1994. At each Annual Meeting of Shareholders after the aforementioned initial classification, the successors to Directors whose terms shall then expire shall be elected to serve from the time of election and qualification until the third Annual Meeting following election and until a successor shall have been duly elected and shall have qualified.

The Directors of any class of Directors of the Corporation may not be removed prior to the expiration date of their terms of office except for cause and by an affirmative vote of at least eighty percent (80%) of the outstanding shares of all classes of capital stock of the Corporation entitled to vote for such member(s) of the Board of Directors at the Annual Meeting of Shareholders or at any Special Meeting of Shareholders called by the Board of Directors or by the Chairman of the Board or by the President for this purpose.

ARTICLE VII

LIMITATION OF DIRECTOR AND OFFICER LIABILITY

To the fullest extent now or hereafter permitted under the New York Business Corporation Law, no director or officer of the Corporation shall be personally liable to the Corporation or its shareholders for monetary damages for any breach of fiduciary duty in such capacity. No amendment or repeal of this Article 7 shall adversely affect any right or protection of any director or officer of the Corporation existing at the time of such amendment or repeal with respect to acts or omissions occurring prior to such amendment or repeal.

ARTICLE VIII

PREEMPTIVE RIGHTS

No holder of Common Shares, or preferred stock of any designation or series shall, as such holder, have any right to purchase or subscribe for (i) any stock of any class, or any warrant or warrants, option or options, or other instrument or instruments that shall confer upon the holder or holders thereof the right to subscribe for or purchase or receive from the Corporation any stock of any class or classes which the Corporation may issue or sell, whether or not such stock shall be convertible into or exchangeable for any other stock of the Corporation of any class or classes and whether or not such stock shall be unissued shares authorized by the Certificate of Incorporation or by any amendment thereto or shares of stock of the Corporation acquired by it after the issuance thereof, or (ii) any obligation which the Corporation may issue or sell that shall be convertible into or exchangeable for any shares of stock of the Corporation of any class or classes, or to which shall be attached or appurtenant to any warrant or warrants, option or options or other instrument or instruments that shall confer upon the holder or holders of such obligation the right to subscribe for or purchase or receive from the Corporation any shares of its stock of any class or classes.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3256

Samsung Bioepis Exhibit 1017, pg. 3256

Upon any issuance for money or other consideration of any stock of the Corporation that may be authorized from time to time, no holder of stock, irrespective of the kind of such stock, shall have any preemptive or other right to subscribe for, purchase or receive any proportionate or other share of the stock so issued, and the Board of Directors may dispose of all or any portion of such stock as and when it may determine free of any such rights, whether by offering the same to shareholders or by sale or other disposition as said Board may deem advisable."

IN WITNESS WHEREOF, this Restated Certificate of Incorporation has been signed as of the 25th day of January, 2008, and affirmed that the statements made herein are true under penalties of perjury.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, President

/s/ Stuart A. Kolinski
Stuart A. Kolinski, Secretary

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3257

Samsung Bioepis Exhibit 1017, pg. 3257

RESTATED CERTIFICATE OF INCORPORATION

OF

REGENERON PHARMACEUTICALS, INC.

UNDER SECTION 807 OF THE BUSINESS CORPORATION LAW

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
ONE RODNEY SQUARE
WILMINGTON, DELAWARE 19801

Exhibit 10.18

Portions of this Exhibit Have Been Omitted and Separately Filed with the Securities And Exchange Commission with a Request For Confidential Treatment

DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT

By and Between

AVENTIS PHARMACEUTICALS INC.

and

REGENERON PHARMACEUTICALS, INC.

Dated as of November 28, 2007

TABLE OF CONTENTS

		Page
	ARTICLE 1 DEFINITIONS	
1.1	"Affiliate"	1
1.2	"Agreement"	2
1.3	"Alliance Manager"	2
1.4	"Antibody"	2
1.5	"Aventis Collaboration Agreement"	2
1.6	"Business Day"	2
1.7	"Commercially Reasonable Efforts"	2
1.8	"Competing Refused Candidate"	2
1.9	"Confidential Information"	2
1.10	"Contract Year"	2
1.11	"CPI"	3
1.12	"Damages"	3
1.13	"Default Interest Rate"	3
1.14	"Disclosing Party"	3
1.15	"Discovery Plan"	3
1.16	"Discovery Program"	3
1.17	"Discovery Program Costs"	3
1.18	"Effective Date"	3
1.19	"Excluded Candidates"	3
1.20	"Executive Officers"	3
1.21	"FDA"	3
1.22	"Force Majeure"	3
1.23	"FTE"	3
1.24	"FTE Cost"	3
1.25	"FTE Rate"	4
1.26	"GAAP"	4
1.27	"Governmental Authority"	4
1.28	"IAS/IFRS"	4
1.29	"IFM"	4
1.30	"Immunoconjugate"	4
1.31	"IND"	4
1.32	"IND Preparation"	4
1.33	"Indemnified Party"	4
1.34	"Indemnifying Party"	4
1.35	"Initial Development Plan"	4
1.36	"Investor Agreement"	4

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3260

Samsung Bioepis Exhibit 1017, pg. 3260

		Page
1.37	"Joint Research Committee" or "JRC"	5
1.38	"Joint Inventions"	5
1.39	"Joint Patent Rights"	5
1.40	"Know-How"	5
1.41	"Law" or "Laws"	5
1.42	"Lead Candidate"	5
1.43	"License and Collaboration Agreement"	5
1.44	"Licensed Product"	5
1.45	"Licensed Refused Sanofi Candidate"	5
1.46	"Manufacturing Cost"	5
1.47	"Maximum Annual Discovery Program Costs"	5
1.48	"Mice"	5
1.49	"Mice-Derived Therapeutic (or Diagnostic) Candidate" or "MTC"	5
1.50	"Modified Clause"	5
1.51	"Net Sales"	5
1.52	"Opt-In Notice"	7
1.53	"Opt-In Period"	7
1.54	"Opt-In Report"	7
1.55	"Opt-In Rights"	7
1.56	"Out-of-Pocket Costs"	7
1.57	"Party" or "Parties"	7
1.58	"Patent Application"	7
1.59	"Patent Rights"	7
1.60	"Patents"	7
1.61	"Person"	7
1.62	"Phase I Clinical Trial"	7
1.63	"Product Candidate"	7
1.64	"Product Patent Rights"	7
1.65	"Program Target"	8
1.66	"Publishing Party"	8
1.67	"Receiving Party"	8
1.68	"Refused Candidate"	8
1.69	"Regeneron"	8
1.70	"Regeneron Indemnitees"	8
1.71	"Regeneron Intellectual Property"	8
1.72	"Regeneron Know-How"	8
1.73	"Regeneron Patent Rights"	8
1.74	"Regeneron Sole Inventions"	8
1.75	"Regeneron Target IP"	8
1.76	"Regulatory Authority"	8
1.77	"Royalty Product"	8
1.78	"Royalty Term"	8
1.79	"Sanofi"	8
1.80	"Sanofi Divested Antibody"	8
1.81	"Sanofi Indemnitees"	8
1.82	"Sanofi Intellectual Property"	9

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3261

Samsung Bioepis Exhibit 1017, pg. 3261

		Page
1.83	"Sanofi Know-How"	9
1.84	"Sanofi Patent Rights"	9
1.85	"Sanofi Sole Inventions"	9
1.86	"Sanofi Sole Projects"	9
1.87	"Sanofi Targets"	9
1.88	"Sanofi Target IP"	9
1.89	"Sole Inventions"	9
1.90	"Solely Developed Immunoconjugate"	9
1.91	"Stock Purchase Agreement"	9
1.92	"Tail Period"	9
1.93	"Target"	9
1.94	"Target List"	9
1.95	"Term"	9
1.96	"Territory"	9
1.97	"Third Party"	10
1.98	"Third Party Opportunities"	10
1.99	"Valid Claim"	10
	ARTICLE 2 DISCOVERY PROGRAM	
2.1	Discovery Program	10
2.2	Term of the Discovery Program	10
2.3	Discovery Plans	10
2.4	Sanofi Targets	11
2.5	Commercially Reasonable Efforts; Compliance with Laws	11
2.6	Exchange of Information	11
2.7	Further Assurances and Transaction Approvals	11
2.8	Exclusive Discovery Program	12
2.9	Tail Period	14
2.10	Research Licenses; Licenses Generally	15
2.11	Immunoconjugates	15
2.12	Sanofi Target Licenses	15
2.13	Non-Exclusive License to Sanofi	15
2.14	Invention Assignment	15
2.15	Supply of VelociGene® Mice	16
2.16	Option for VelocImmune® License	16
2.17	Option for **********, and other Antibody Know How Licenses	16
2.18	Third Party Platform Licenses	16
	ARTICLE 3 JOINT RESEARCH COMMITTEE	
3.1	The Joint Research Committee	16
3.2	Alliance Management	18
3.3	Resolution of Governance Matters	18
3.4	Obligations of the Parties and their Affiliates	19

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3262

Samsung Bioepis Exhibit 1017, pg. 3262

		Page
	ARTICLE 4 PAYMENTS	
4.1	Upfront Payment	19
4.2	Discovery Program Costs	19
4.3	Reports and Discovery Program Cost Payments	20
4.4	Royalty Payments for Royalty Products	20
4.5	Royalty Reporting	20
4.6	Payment Method and Currency	21
4.7	Late Payments	21
4.8	Taxes	21
	ARTICLE 5 OPT-IN RIGHTS TO LICENSE PRODUCT CANDIDATES	
5.1	Opt-In Rights to License Product Candidates	21
5.2	Process for Opt-In Rights	22
5.3	Initial Development Plan	22
5.4	Opt-In Exercise	22
5.5	Dll4 and REGN-88	22
5.6	Refused Candidates	22
	ARTICLE 6 NEWLY CREATED INVENTIONS	
6.1	Ownership of Newly Created Intellectual Property	23
6.2	Prosecution and Maintenance of Patent Rights	25
6.3	Third Party Claims	26
	ARTICLE 7 BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS	
7.1	Books and Records	26
7.2	Audits and Adjustments	27
7.3	IAS/IFRS/GAAP	27
	ARTICLE 8 REPRESENTATIONS, WARRANTIES AND COVENANTS	
8.1	Joint Representations and Warranties	27
8.2	Knowledge of Pending or Threatened Litigation	28
8.3	Additional Regeneron Representations, Warranties and Covenants	28
8.4	Disclaimer of Warranties	29
	ARTICLE 9 CONFIDENTIALITY	
9.1	Confidential Information	29

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3263

Samsung Bioepis Exhibit 1017, pg. 3263

		Page
9.2	Injunctive Relief	31
9.3	Publications	31
9.4	Disclosures Concerning this Agreement	31
	ARTICLE 10 INDEMNITY	
10.1	Indemnity and Insurance	32
10.2	Indemnity Procedure	33
	ARTICLE 11 FORCE MAJEURE	
	ARTICLE 12 TERM AND TERMINATION	
12.1	Term	35
12.2	Termination For Material Breach	35
12.3	Termination for Insolvency	35
12.4	Termination by Sanofi on Notice	36
12.5	Termination for Breach of Standstill	36
12.6	Termination for Breach of License and Collaboration Agreement	36
12.7	Effect of Termination by Sanofi for Breach	36
12.8	Effect of Termination by Regeneron for Breach	37
12.9	Survival of Obligations	38
12.10	Return of Confidential Information	38
12.11	Special Damages	39
12.12	Termination by Sanofi At Will	39
	ARTICLE 13 Arbitration	
13.1	Binding Arbitration	39
	ARTICLE 14 MISCELLANEOUS	
14.1	Governing Law; Submission to Jurisdiction	41
14.2	Waiver	41
14.3	Notices	41
14.4	Entire Agreement	41
14.5	Amendments	41
14.6	Interpretation	42
14.7	Severability	42
14.8	Assignment	42
14.9	Successors and Assigns	42
14.10	Affiliates	42
14.11	Counterparts	43

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3264

Samsung Bioepis Exhibit 1017, pg. 3264

		Page
14.12	Third Party Beneficiaries	43
14.13	Relationship of the Parties	43
14.14	Limitation of Damages	43
14.15	Non-Solicitation	43
14.16	No Strict Construction	44

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3265

Samsung Bioepis Exhibit 1017, pg. 3265

Exhibit 10.18

DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT

THIS DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT ("Agreement"), dated as of November 28, 2007 (the "Effective Date"), is by and between AVENTIS PHARMACEUTICALS INC. ("Sanofi"), a corporation organized under the laws of Delaware, having a principal place of business at 55 Corporate Boulevard, Bridgewater, New Jersey 08807, an indirect wholly owned subsidiary of Sanofi-Aventis, a company organized under the laws of France with its principal headquarters at 174, avenue de France, 75103 Paris, France ("Sanofi Parent"), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591, USA ("Regeneron") (with each of Sanofi and Regeneron referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, Regeneron plans to undertake a broad therapeutic antibody discovery and development program with the objective of identifying and validating potential drug discovery targets for the purpose of discovering fully human monoclonal antibody product candidates against those targets using its proprietary VelocImmune® and related suite of technologies; and

WHEREAS, Sanofi is interested in funding and assisting with Regeneron's plans to discover and validate potential drug discovery targets for the purpose of discovering fully human monoclonal antibody product candidates in exchange for an option to license certain rights to the resulting fully human monoclonal antibodies under the terms set forth in this Agreement and in the License and Collaboration Agreement (as further defined in Article 1 below) to be entered into between the parties contemporaneously with the execution of this Agreement;

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by, or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract, or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of

certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates nor shall Regeneron or any of its Affiliates be deemed Affiliates of Sanofi or any of its Affiliates. For purposes of this Agreement, neither Sanofi Pasteur nor Merial Limited, nor any of their respective subsidiaries or joint ventures, shall be deemed to be Affiliates of Sanofi or any of its Affiliates.

1.2 "Agreement" shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.

1.3 "Alliance Manager" shall have the meaning set forth in Section 3.2.

1.4 "Antibody" shall mean **********, and any composition or formulation that incorporates or includes any of the foregoing.

1.5 "Aventis Collaboration Agreement" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between sanofi-aventis US (as successor in interest to Sanofi) and Regeneron, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, and Section 11.2 of the Stock Purchase Agreement, as the same may be further amended from time to time.

1.6 "Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, United States or Paris, France are authorized or required by Law to remain closed.

1.7 "Commercially Reasonable Efforts" shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a Target-by-Target and Antibody-by-Antibody (including MTCs) basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors.

1.8 "Competing Refused Candidate" shall mean any Refused Candidate having the same Target as a Licensed Product (as long as such Licensed Product is licensed to Sanofi under the License and Collaboration Agreement).

1.9 "Confidential Information" shall have the meaning set forth in Section 9.1.

1.10 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2008, and each succeeding twelve (12) month period thereafter during the term

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3267

Samsung Bioepis Exhibit 1017, pg. 3267

of the Discovery Program (except that the last Contract Year shall end on the effective date of any termination or expiration of this Agreement).

1.11 "CPI" shall mean the Consumer Price Index — All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

1.12 "Damages" shall have the meaning set forth in Section 10.1(a).

1.13 "Default Interest Rate" shall have the meaning set forth in Section 4.7.

1.14 "Disclosing Party" shall have the meaning set forth in Section 9.1.

1.15 "Discovery Plan" shall have the meaning set forth in Section 2.3.

1.16 "Discovery Program" shall mean all research and development activities to be performed under this Agreement **********.

1.17 "Discovery Program Costs" shall mean all Out-of-Pocket Costs, FTE Costs and Manufacturing Costs incurred by Regeneron, after the Effective Date directly in connection with the performance of the Discovery Program (and, as such costs relate to a particular Licensed Product, ending on the last day of the month preceding the month in which the Opt-In Notice for such Licensed Product is received by Regeneron).

1.18 "Effective Date" shall have the meaning set forth in the introductory paragraph.

1.19 "Excluded Candidates" shall mean Antibodies (including MTCs) against Targets set forth in Schedule 1.19 as of the Effective Date and those Targets that will be notified by Sanofi to Regeneron pursuant to the second sentence of Section 2.8(b)(i).

1.20 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the most senior Research and Development Officer of Sanofi Parent, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.

1.21 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.22 "Force Majeure" shall have the meaning set forth in Article 11.

1.23 "FTE" shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed by Regeneron (or its Affiliate) who performs work under the Discovery Program, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be ******** hours per year.

1.24 "FTE Cost" shall mean, for all activities performed under the Discovery Program, the product of (a) the number of FTEs performing activities under the Discovery Program and (b) the FTE Rate.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3268

Samsung Bioepis Exhibit 1017, pg. 3268

1.25 "FTE Rate" shall mean $***** in the first Contract Year, such amount to be adjusted as of January 1, 2009 and annually thereafter by the sum of (a) the percentage increase or decrease, if any, in the CPI for the twelve (12) months ending June 30 of the Contract Year prior to the Contract Year for which the adjustment is being made, **********.

1.26 "GAAP" shall mean generally accepted accounting principles as applicable in the United States.

1.27 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body, or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city, or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.28 "IAS/IFRS" shall mean International Financial Reporting Standards adopted by the International Accounting Standards Board.

1.29 "IFM" shall have the meaning set forth in Section 2.11(d)(ii).

1.30 "Immunoconjugate" shall mean an Antibody (or derivative or fragment thereof) linked to a cytotoxic or any molecule potentially able to enhance the therapeutic activity of such Antibody (or derivative or fragment thereof).

1.31 "IND" shall mean, with respect to each Product Candidate, an Investigational New Drug Application filed with the FDA with respect to such Product Candidate pursuant to 21 C.F.R. § 312 before the commencement of clinical trials involving such Product Candidate, including all amendments and supplements to such application, or any equivalent filing with any Regulatory Authority outside the United States.

1.32 "IND Preparation" shall mean all drug development activities in support of a Lead Candidate or Product Candidate up to the filing of the IND for the Phase I Clinical Trial, including, but not limited to, assay development, sample analysis, preclinical toxicology, preclinical pharmacokinetics and toxicokinetics, pharmacological assessment (if applicable), cell line development and protein chemistry sciences, formulation development, clinical trial protocol development, IND drafting and data compilation, and manufacturing preclinical and clinical supplies.

1.33 "Indemnified Party" shall have the meaning set forth in Section 10.2(a).

1.34 "Indemnifying Party" shall have the meaning set forth in Section 10.2(a).

1.35 "Initial Development Plan" shall have the meaning set forth in Section 5.3.

1.36 "Investor Agreement" shall mean the Investor Agreement by and between (a) Sanofi, Sanofi Parent, sanofi-aventis US LLC, and Sanofi-Aventis Amerique du Nord and (b) Regeneron, substantially in the form of Exhibit B to the Stock Purchase Agreement, which will be entered into concurrently with the closing under the Stock Purchase Agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3269

Samsung Bioepis Exhibit 1017, pg. 3269

1.37 "Joint Research Committee" or "JRC" shall mean the Joint Research Committee described in Section 3.1(a).

1.38 "Joint Inventions" shall have the meaning set forth in Section 6.1(b).

1.39 "Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.

1.40 "Know-How" shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information (whether or not patentable or otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party's Patents or Patent Applications.

1.41 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions, and/or ordinances of any Governmental Authority in the Territory.

1.42 "Lead Candidate" shall mean, for any Program Target, each Antibody, including MTCs, that satisfies the applicable criteria set forth in Schedule 1.42 and is selected by Regeneron to begin IND Preparation under this Agreement.

1.43 "License and Collaboration Agreement" shall mean the License and Collaboration Agreement between the Parties, dated as of the date of this Agreement, the terms of which are incorporated by reference into, and are part of, this Agreement.

1.44 "Licensed Product" shall mean any Product Candidate for which Sanofi has exercised its Opt-In Rights pursuant to Section 5.4 below.

1.45 "Licensed Refused Sanofi Candidate" shall have the meaning set forth in Section 2.12.

1.46 "Manufacturing Cost" shall mean the fully burdened cost (without mark-up) of manufacturing Product Candidates and Lead Candidates for preclinical activities and Phase I Clinical Trials (and, if agreed by the Parties other clinical trials), and the cost for providing dedicated manufacturing capacity for Lead Candidates and Product Candidates, in each case, as calculated in accordance with Schedule 1.46.

1.47 "Maximum Annual Discovery Program Costs" shall have the meaning set forth in Section 4.2.

1.48 "Mice" shall mean **********.

1.49 "Mice-Derived Therapeutic (or Diagnostic) Candidate" or "MTC" shall mean any Antibody derived from Mice.

1.50 "Modified Clause" shall have the meaning set forth in Section 14.7.

1.51 "Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of Royalty Products in the Territory by or on behalf of a Party, or its Affiliates or sublicensees to

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3270

Samsung Bioepis Exhibit 1017, pg. 3270

Third Parties, less the following deductions, determined in accordance with IAS/IFRS (or GAAP for the US) consistently applied:

(a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Royalty Products;

(b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;

(c) chargebacks and other amounts paid on sale or dispensing of Royalty Products;

(d) Third Party cash rebates and chargebacks related to sales of Royalty Products, to the extent allowed;

(e) retroactive price reductions that are actually allowed or granted;

(f) compulsory refunds, credits and rebates directly related to the sale of Royalty Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or governmental regulations;

(g) freight, postage, shipment and insurance costs (or wholesaler fees in lieu of those costs) and customs duties incurred in delivering Royalty Products that are separately identified on the invoice or other documentation;

(h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of Royalty Products, which are separately identified on the invoice or other documentation;

(i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such Royalty Product falling within categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof;

(j) invoiced amounts that are written off as uncollectible in accordance with a Party's or its Affiliates' or sublicensees' respective accounting principles as applied consistently

Net Sales in currency other than United States Dollars shall be translated into United States Dollars according to the provisions of Section 4.6 of this Agreement.

Sales between the Parties, or between the Parties and their Affiliates or sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Royalty Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if a Party or its Affiliates or sublicensee sells such Royalty Products in the form of a combination

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3271

Samsung Bioepis Exhibit 1017, pg. 3271

product containing any Royalty Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), then prior to the first commercial sale of such Combination Product, the Parties shall agree on the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, Immunoconjugates shall not be deemed Combination Products.

1.52 "Opt-In Notice" shall have the meaning set forth in Section 5.4.

1.53 "Opt-In Period" shall have the meaning set forth in Section 5.4.

1.54 "Opt-In Report" shall have the meaning set forth in Section 5.2.

1.55 "Opt-In Rights" shall have the meaning set forth in Section 5.1.

1.56 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP) by Regeneron (or its Affiliate) directly in connection with the performance of the Discovery Program.

1.57 "Party" or "Parties" shall have the meaning set forth in the introductory paragraph.

1.58 "Patent Application" shall mean any application for a Patent.

1.59 "Patent Rights" shall mean unexpired Patents and Patent Applications.

1.60 "Patents" shall mean patents together with all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations, extensions, registrations, patent term adjustments or extensions, supplemental protection certificates and renewals of any of the foregoing, and all counterparts thereof in any country in the Territory.

1.61 "Person" shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.

1.62 "Phase I Clinical Trial" shall mean the first clinical trial of a Product Candidate following IND Preparation.

1.63 "Product Candidate" shall mean any Lead Candidate that substantially completes IND Preparation and is ready to be offered for license to Sanofi under the Opt-In Rights.

1.64 "Product Patent Rights" shall mean any Patent or Patent Application having a specification which supports a claim that may be infringed by making, using, selling, importing or exporting a Lead Candidate or Product Candidate in the Discovery Program, including, without limitation, any derivatives, fragments, compositions of matter or uses, thereof.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3272

Samsung Bioepis Exhibit 1017, pg. 3272

1.65 "Program Target" shall mean a Target that is selected by Regeneron, subject to Section 2.4, as a Target against which Antibodies are to be generated under the Discovery Program.

1.66 " Publishing Party" shall have the meaning set forth in Section 9.3.

1.67 " Receiving Party "shall have the meaning set forth in Section 9.1.

1.68 " Refused Candidate" shall have the meaning set forth in Section 5.6 (i).

1.69 "Regeneron" shall have the meaning set forth in the introductory paragraph.

1.70 " Regeneron Indemnitees" shall have the meaning set forth in Section 10.1(a).

1.71 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and the Regeneron Know-How.

1.72 "Regeneron Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Know-How and Know-How included in Joint Inventions) with the right to sublicense the same necessary or useful for the performance of the Discovery Program.

1.73 "Regeneron Patent Rights" shall mean those Patent Rights now or hereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Patent Rights and Patent Rights included in Joint Inventions) with the right to sublicense the same and which include at least one (1) claim which would be infringed by the research, development, manufacture or use of the Mice or any Target, Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program.

1.74 "Regeneron Sole Inventions" shall have the meaning set forth in Section 6.1(a).

1.75 "Regeneron Target IP" shall mean **********.

1.76 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the activities conducted under the Discovery Program.

1.77 "Royalty Product" shall mean **********.

1.78 " Royalty Term "shall have the meaning set forth in Section 4.5.

1.79 "Sanofi "shall have the meaning set forth in the introductory paragraph.

1.80 " Sanofi Divested Antibody" shall have the meaning set forth in Section 2.8(b)(vii).

1.81 " Sanofi Indemnitees " shall have the meaning set forth in Section 10.1(b).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3273

Samsung Bioepis Exhibit 1017, pg. 3273

1.82 "Sanofi Intellectual Property" shall mean the Sanofi Patent Rights and the Sanofi Know-How.

1.83 "Sanofi Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program (including the Tail Period) owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Know-How and Know-How included in Joint Inventions) with the right to sublicense the same necessary or useful for the performance of the Discovery Program.

1.84 "Sanofi Patent Rights" shall mean those Patent Rights now or hereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Patent Rights and Patent Rights included in Joint Inventions) with the right to sublicense the same and which include at least one (1) claim which would be infringed by the research, development, manufacture or use of the Mice or any Target, Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program.

1.85 "Sanofi Sole Inventions" shall have the meaning set forth in Section 6.1(a).

1.86 "Sanofi Sole Projects" shall have the meaning set forth in Section 2.8(b)(iii).

1.87 "Sanofi Targets" shall have the meaning set forth in Section 2.4.

1.88 "Sanofi Target IP" shall mean **********.

1.89 "Sole Inventions" shall have the meaning set forth in Section 6.1(a).

1.90 "Solely Developed **********." shall have the meaning set forth in Section 2.11(b).

1.91 "Stock Purchase Agreement" shall mean the Stock Purchase dated as of the Effective Date by and between (a) Sanofi, sanofi-aventis US LLC, and Sanofi-Aventis Amerique du Nord and (b) Regeneron.

1.92 "Tail Period" shall have the meaning set forth in Section 2.9.

1.93 "Target" shall mean any gene, receptor, ligand, or other molecule (a) potentially associated with a disease activity, and (b) which potentially has a biological activity that is modified by direct interaction with an Antibody, including any MTC, or (c) to which an Antibody, including any MTC, binds.

1.94 "Target List" shall mean the list of Targets in the Discovery Program, including a description of the stage of discovery or pre-clinical development of each such Target in the Discovery Program, which list shall be in the form attached as Schedule 1.94, and which list shall be updated by the JRC on a quarterly basis in accordance with Section 3.1(c) below.

1.95 "Term" shall have the meaning set forth in Section 12.1.

1.96 "Territory" shall mean all the countries and territories of the world.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3274

Samsung Bioepis Exhibit 1017, pg. 3274

1.97 "Third Party" shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

1.98 "Third Party Opportunities" shall have the meaning set forth in Section 2.8(a)(ii).

1.99 "Valid Claim" shall mean a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Government Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.

ARTICLE 2
DISCOVERY PROGRAM

2.1 Discovery Program. The objective of the Parties during the Discovery Program is for Regeneron to discover, identify and/or validate Targets from which to select Program Targets, generate Antibodies, including MTCs, against such Program Targets (including Program Targets that are Sanofi Targets) from which to select Lead Candidates, and develop them through IND Preparation to offer to Sanofi for joint development and commercialization under the terms set forth herein and in the License and Collaboration Agreement. During the first five (5) years of the Discovery Program, Regeneron will use Commercially Reasonable Efforts (i) to discover, identify and validate Targets and (ii) to select Program Targets for review and discussion by the JRC pursuant to Section 3.1 herein. **********. Regeneron will use Commercially Reasonable Efforts to manufacture preclinical and clinical supplies of the Lead Candidates and Product Candidates for the Discovery Program and the Phase 1 Clinical Trial. The JRC will prioritize the Antibodies, including MTCs, to be further pursued as Lead Candidates, and Regeneron will commence IND Preparation activities only for those Antibodies, including MTCs, that meet the applicable criteria set forth in Schedule 1.42. The JRC will evaluate, select and prioritize Targets for the Target List. However, Regeneron will have the right to conduct Target discovery and validation on Targets as part of the Discovery Program before they are formally approved by the JRC for selection on the Target List but shall notify the JRC of any new Target at the next meeting of the JRC. Subject to Sanofi's selection rights under Section 3.1(e) and the other terms of this Agreement, Regeneron will have sole responsibility for the design and conduct of all activities under the Discovery Program, including, without limitation, decisions relating to initiation and termination of programs and activities, manufacturing activities, and staffing and resource allocation between different programs and activities in the Discovery Program. Sanofi, through the JRC, will provide consultation and advice to support Regeneron's efforts.

2.2 Term of the Discovery Program. The Discovery Program shall commence on the Effective Date and shall end on December 31, 2012 unless (a) terminated earlier in accordance with the provisions of this Agreement or (b) extended by Sanofi for the Tail Period pursuant to the terms of Section 2.9.

2.3 Discovery Plans. Regeneron will prepare an annual research discovery and pre-clinical development plan (the "Discovery Plan") for the Discovery Program setting forth the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3275

Samsung Bioepis Exhibit 1017, pg. 3275

overall strategy, plans, and estimated budget for the Discovery Program for the ensuing Contract Year, which it will submit to the JRC for review and comment. For each Lead Candidate, the Discovery Plan will include activities and a planned timeline for IND Preparation. Regeneron shall consider in good faith comments on the Discovery Plan from Sanofi's representatives on the JRC. Except for the initial Discovery Plan (which will be provided to the JRC within sixty (60) days of the Effective Date), Regeneron will present an updated Discovery Plan to the JRC at least two (2) months prior to the end of each Contract Year.

2.4 Sanofi Targets. In the event that at any time the JRC is unable to agree on the Targets to include on the Target List, Sanofi will have the right to select and maintain in each update to the Target List up to ********** of the Targets included under the following headings of the Target List: **********. Neither Regeneron nor Regeneron's representatives on the JRC shall have the right to reject, replace, or discriminate against such Sanofi Targets without the agreement of Sanofi's representatives on the JRC. Sanofi shall provide Regeneron's representatives on the JRC with its proposed list of Targets at least ten (10) Business Days before each JRC meeting for consideration by the JRC and, if necessary, selection by Sanofi to make up its ********** of the Target List as described in this Section 2.4.

2.5 Commercially Reasonable Efforts; Compliance with Laws. During the term of the Discovery Program, Regeneron will use Commercially Reasonable Efforts to discover and develop Product Candidates to offer for license to Sanofi pursuant to the Opt-In Rights. Without limiting the foregoing, Regeneron will use Commercially Reasonable Efforts to identify Lead Candidates and complete IND Preparation for Lead Candidates in a timely manner during the term of the Discovery Program. Each Party hereby covenants and agrees to comply with applicable Laws in performing activities connected with the Discovery Program.

2.6 Exchange of Information. Regeneron will share information with the JRC in a timely manner concerning the progress of the Discovery Program consistent with Section 3.1(b). Without limiting the foregoing, at least five (5) calendar days prior to each regular quarterly meeting of the JRC, Regeneron will use its Commercially Reasonable Efforts to provide to Sanofi's representatives on the JRC a written report (in electronic form) summarizing the material activities undertaken by Regeneron in connection with the Discovery Plan, including information concerning new Targets proposed for the Target List, new Program Targets, new Lead Candidates and new Product Candidates. In addition, Regeneron will provide Sanofi with proposed Targets for inclusion on the updated Target List and Target proposed not to be pursued further under the Discovery Program at least ten (10) Business Days prior to each regular quarterly meeting of the JRC. Sanofi shall have the right to reasonably request and to receive in a timely manner clarifications and answers to questions with respect to such reports and any other data or information it reasonably requests with respect to the conduct of the Discovery Program.

2.7 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3276

Samsung Bioepis Exhibit 1017, pg. 3276

authorizations, or orders required to be obtained or made in connection with the authorization, execution, and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings, including by providing copies of all such non-confidential documents to the other Party and its advisors prior to the filing and, if requested, by accepting all reasonable additions, deletions, or changes suggested in connection therewith. Each Party will furnish all information required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.8 Exclusive Discovery Program.

(a) Exclusivity.

(i) General. Subject to the other subparagraphs in this Section 2.8, **********.

(ii) Third Party Opportunities. Subject to the other sub-paragraphs in this Section 2.8, as part of the Discovery Program, the Parties may evaluate new Targets, Antibodies, and antibody technologies owned or controlled by Third Parties ("Third Party Opportunities") to determine whether such Targets, Antibodies or antibody technologies should be licensed or acquired by the Parties for the Discovery Program. Should a Party identify such a Third Party Opportunity that it is interested in acquiring or licensing for inclusion in the Discovery Program, it shall notify the other Party for consideration and discussion. If the Parties approve the inclusion of such Third Party Opportunity in the Discovery Program, the Parties shall decide which Party will license or otherwise acquire rights to the Third Party Opportunity and include the applicable Target, Antibody or antibody technology, as the case may be, in the Discovery Program.
**********.

(b) Exclusions. Notwithstanding subsection (a) above, the following shall apply:

(i) Excluded Candidates. Regeneron (and its Affiliates) shall have the right to develop and commercialize Excluded Candidates of Regeneron as listed in Schedule 1.19 either on its own or with Third Parties outside the Discovery Program without restriction under this Agreement, and Sanofi (and its Affiliates) shall have the right to develop and commercialize Excluded Candidates of Sanofi listed in paragraph A of Schedule 1.19 on its own or with Third Parties outside the Discovery Program without restriction under this Agreement.
**********. For the avoidance of doubt, each Party shall have the right to develop and commercialize Antibodies (including, in the case of Regeneron, MTCs) against Targets of the other Party's Excluded Candidates on its own or with Third Parties outside the Discovery Program without restriction under this Agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3277

Samsung Bioepis Exhibit 1017, pg. 3277

(ii) Refused Candidates. Regeneron (and its Affiliates) shall have the right to develop and commercialize Refused Candidates outside the Discovery Program as set forth in Section 5.6 below, unless **********.

(iii) Sanofi Sole Projects. Sanofi shall only be entitled to take a total of up to ********** into development outside the Discovery Program, such Antibodies being defined as the "Sanofi Sole Projects". Sanofi Sole Projects may be generated from either its internal research and/or its acquisition from Third Parties as follows:

(1) Antibodies. Sanofi and its Affiliates shall have the right to develop and commercialize Antibodies outside the Discovery Program (including Antibodies licensed or acquired from a Third Party or through the acquisition of a Third Party that owns or controls an Antibody), provided that, such Antibodies are not against Targets on the Target List. Sanofi shall notify Regeneron in writing of the Target(s) for each such Antibody at the time **********. Regeneron and its Affiliates shall have the right to discover, develop and commercialize Antibodies (including MTCs) against any such Target(s) without restriction under this Agreement outside the Discovery Program and this Agreement; or

(2) Targets. Sanofi shall be entitled to discover Targets that are not on the Target List and to exclude from the Target List, Targets proposed by Regeneron for the Target List, if such Targets **********. In order to exclude such Targets, Sanofi must provide written notice of such exclusion to Regeneron within sixty (60) days after its receipt of the Regeneron proposal together with a signed certificate from an officer of Sanofi Parent certifying that **********. Each Party and their respective Affiliates shall have the right to discover, develop, and commercialize Antibodies (including, in the case of Regeneron, MTCs) against any such Target outside the Discovery Program without restriction under this Agreement. **********. Sanofi shall notify Regeneron's representatives on the JRC before initiating discovery efforts on a Target other than a Sanofi Target to be included in the Discovery Program that was formerly on the Target List (but is no longer on the Target List), to determine whether Regeneron's representatives on the JRC are interested in reinitiating discovery or validation activities against such Target as part of the Discovery Program.

(iv) Third Party Antibodies In Development. Sanofi and its Affiliates shall have the right to develop and commercialize an acquired Antibody (whether such acquisition is by direct acquisition, by license or through the acquisition of a Third Party that owns or controls an Antibody(ies) (the "Acquired Antibody") that at the time of acquisition **********. Sanofi shall notify promptly Regeneron of such acquisition or license (including the identity of the Target) and may continue the development of such Acquired Antibody and other Antibodies

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3278

Samsung Bioepis Exhibit 1017, pg. 3278

against such Target without restriction outside of the Discovery Program and this Agreement. In the event of such an acquisition or license by Sanofi, the applicable Target shall no longer be a deemed a Program Target and shall be removed from the Target List, and Sanofi shall no longer have any rights to any Antibodies, including MTCs, against such Target under this Agreement. Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any MTCs or other Antibodies against such Target and may practice and use any Regeneron Intellectual Property, including, without limitation, the Mice, in connection with such activities, without restriction outside the Discovery Program and this Agreement. **********.

(v) Company Acquisitions For clarification, where Sanofi or its Affiliates acquire rights to an Acquired Antibody by the acquisition of a Third Party or part or the whole of its business, Sanofi may as an alternative to any rights under Sections 2.8(b)(iii) and (iv) above, either include the applicable Target for the Acquired Antibody on the Target List (either with Regeneron's consent or as one of the Sanofi Targets), or commit in writing to Regeneron to divest such Acquired Antibody (by sale or license) within **********.

(vi) Regulatory Divestitures. In the event that Sanofi acquires rights to an Acquired Antibody as a result of its acquisition of a Third Party and believes, based on the reasonable advice of its outside legal counsel, that it is required by Law to divest its interest in the Antibodies against such Target in the Discovery Program, then Sanofi shall have the right to exclude such Target from the Discovery Program, and develop and commercialize such Acquired Antibodies outside the Discovery Program and the terms of this Agreement. Sanofi shall no longer have any rights to any Antibodies, including MTCs, against such Target under this Agreement ("Sanofi Divested Antibodies"); however, **********. Either Party shall have the right to develop and commercialize Antibodies against the applicable Target(s) outside the Discovery Program and the terms of this Agreement, and Regeneron shall have and retain exclusive rights to any Antibodies, including MTCs, discovered in the Discovery Program against such Target without restrictions under this Agreement.

(vii) **********.

(viii) **********.

2.9 Tail Period. At Sanofi's sole option, upon prior written notice to Regeneron, such notice to be delivered no later than June 30, 2012 (**********) (as applicable, the "Tail Period Notice Date"), the term of the Discovery Program may be extended for up to three (3) additional years (as designated by Sanofi in its notice) (the "Tail Period"). If Sanofi fails to provide such written notice by the applicable Tail Period Notice Date, the Discovery Program shall expire on December 31, 2012 (**********). Sanofi

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3279

Samsung Bioepis Exhibit 1017, pg. 3279

shall identify in its written notice the specific Program Targets, Lead Candidates, and Product Candidates to be included in the Discovery Program during the Tail Period. Within ninety (90) days of receipt of Sanofi's notice, the Parties shall agree on a plan and budget (which shall be on a cost basis) to perform the activities set forth below and as requested by Sanofi to be carried out for each Contract Year of the Tail Period. In the event the Parties do not agree on the commercial reasonableness of such budget, then such dispute shall be referred to binding arbitration pursuant to the provisions of Article 13. During the Tail Period, Regeneron will use Commercially Reasonable Efforts **********.

2.10 Research Licenses; Licenses Generally. Each Party hereby grants to the other Party and its Affiliates a non-exclusive, non-transferable, worldwide, royalty-free, research license, without the right to sublicense, under the Regeneron Intellectual Property and the Sanofi Intellectual Property, respectively, solely to perform the Discovery Program. For the avoidance of doubt, neither Party shall use the licenses granted in this Section 2.10 for the benefit, directly or indirectly, of any Third Party. Except as expressly provided for herein, nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights of the other Party (either expressly or by implication or estoppel). Except as expressly provided for in this Section 2.10 or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights or Know-How, either expressly or by implication, estoppel or otherwise. Upon expiration or earlier termination of the Discovery Program, the licenses granted in Section 2.10 herein shall automatically terminate.

2.11 Immunoconjugates. **********.

2.12 Sanofi Target Licenses. With respect to any Product Candidate against a Sanofi Target that becomes a Refused Candidate ("Licensed Refused Sanofi Candidate") or any Sanofi Divested Antibody, Sanofi hereby grants to Regeneron a non-transferable, non-exclusive, worldwide, royalty-bearing (in accordance with Section 4.4 herein) license, with the right to sublicense, under the Sanofi Target IP solely to make, have made, use, sell, offer to sell and import such Licensed Refused Sanofi Candidate or Sanofi Divested Antibody, as the case may be.

Where such Licensed Refused Sanofi Candidate is an Immunoconjugate, then **********.

2.13 Non-Exclusive License to Sanofi. Regeneron hereby grants Sanofi and its Affiliates a worldwide, non-exclusive, non-transferable, royalty-free license, without the right to sublicense, under Regeneron Intellectual Property discovered directly in connection with the performance of the Discovery Program claiming Targets on the Target List and/or methods of use related to the inhibition or use of such Targets for use by Sanofi and its Affiliates in connection with the manufacture, use, sale, offer to sell, and import of small molecule drug and diagnostic products.

2.14 Invention Assignment. All of the employees, officers and consultants of each Party that are supporting the performance of its obligations under this Agreement shall have executed agreements or have existing obligations under law requiring, in the case of employees

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3280

Samsung Bioepis Exhibit 1017, pg. 3280

and officers, assignment to such Party of all inventions made during the course of and as the result of their association with such Party and, in the case of employees, officers and consultants, obligating the individual to maintain as confidential such Party's Confidential Information which such Party may receive, to the extent required to support such Party's obligations under this Agreement.

2.15 Supply of VelociGene® Mice. Within ninety (90) days of the Effective Date or as otherwise mutually agreed by the Parties in writing, the Parties shall enter into a "Mouse Purchase Agreement" pursuant to which Regeneron will use its proprietary technology for the production of genetically modified mouse embryonic stem cell lines and mice derived from the corresponding mouse stem cell lines for Sanofi. The commercial terms of the "Mouse Purchase Agreement" are outlined in Exhibit B.

2.16 Option for VelocImmune® License. At Sanofi's request within sixty (60) days of the fifth anniversary of the Effective Date (or the third anniversary of the Effective Date in the event that Sanofi terminates this Agreement in accordance with Section 12.4), the Parties shall enter into a License and Material Transfer Agreement (the "License and MTA") under which Regeneron will license VelocImmune to Sanofi. **********. As used in this Section 2.16, VelocImmune shall mean Regeneron's Mice technology as previously licensed by Regeneron to Third Parties as of the Effective Date. The License and MTA shall contain such other customary terms and conditions consistent with those included in Regeneron's VelocImmune license agreements existing as of the Effective Date.

2.17 Option for **********Licenses. To the extent that Regeneron decides to license either its **********technologies or other Antibody Know How (any such technologies and Know How being licensed by Regeneron, being referred to as the "Additional Technologies) to commercial entities, then at Sanofi's request, at any time between the fifth anniversary of the Effective Date (**********) and one hundred eighty (180) days following the expiration or earlier termination of the Discovery Program, the Parties shall enter into a definitive agreement under which Regeneron will license the applicable Additional Technologies to Sanofi. The definitive agreement(s) for the Additional Technologies to be licensed to Sanofi shall contain commercial and other terms and conditions that are not materially less favorable, when taken as a whole, than those included in any then-existing license agreements with Third Parties for such Additional Technologies, if any.

2.18 Third Party Platform Licenses. **********.

ARTICLE 3
JOINT RESEARCH COMMITTEE

3.1 The Joint Research Committee.

(a) Formation, Composition and Membership. Within thirty (30) days after the Effective Date, the Parties will establish the JRC, which shall consist of at least three (3) senior representatives appointed by each of Regeneron and Sanofi. Each Party may replace its Committee members upon written notice to the other Party; provided that such replacement is of

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3281

Samsung Bioepis Exhibit 1017, pg. 3281

comparable standing and authority within that Party's organization as the person he or she is replacing (or is otherwise reasonably acceptable to the other Party). The JRC will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi.

(b) Meetings of the JRC. The JRC shall hold an initial joint meeting within forty-five (45) days of the Effective Date or as otherwise agreed by the Parties. Thereafter, the JRC shall meet at least once every calendar quarter, unless the JRC co-chairpersons otherwise agree. All JRC meetings may be conducted by telephone, video-conference or in person as determined by the JRC co-chairpersons; provided, however, that the JRC shall meet in person at least once each calendar year, unless the Parties mutually agree to meet by alternative means. Unless otherwise agreed by the Parties, all in-person meetings for JRC shall be held on an alternating basis between Regeneron's facilities and Sanofi's facilities. Further, each co-chairperson shall be entitled to call meetings in addition to the regularly scheduled quarterly meetings. The co-chairpersons, with the assistance of the Alliance Managers, shall coordinate activities to prepare and circulate an agenda in advance of each meeting and prepare and issue draft minutes of each meeting within fourteen (14) days thereafter and final minutes within thirty (30) days thereafter, such final minutes to include the updated Target List. With the consent of the Parties (not to be unreasonably withheld or delayed), a reasonable number of other representatives of a Party may attend any JRC meeting as non-voting observers (provided that such additional representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in Article 9 below). Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in JRC meetings.

(c) Duties. The JRC shall:

(i) discuss the objectives of the Discovery Program;

(ii) review and comment on the Discovery Plan;

(iii) exchange and review scientific information and data relating to the activities being conducted under, and the then-current progress of, the Discovery Program, including the exchange and review of data and other information resulting from the Discovery Program, and establish processes for the exchange of information relating to the progress of the Discovery Program;

(iv) discuss experiments believed by a Party's representatives on the JRC to be necessary to properly evaluate Program Targets, Lead Candidates and Product Candidates;

(v) provide assistance and recommendations on the direction of the Discovery Program;

(vi) evaluate, select and prioritize Targets proposed by each Party for inclusion on the initial Target List and all quarterly updates thereto (subject to Section 2.4, which updates shall conform to the format of the Target List;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3282

Samsung Bioepis Exhibit 1017, pg. 3282

(vii) discuss whether an Antibody, including any MTC, satisfies the criteria of Lead Candidates attached in Schedule 1.42;

(viii) review and prioritize Lead Candidates;

(ix) consider and act upon such other matters as specified in this Agreement or as otherwise agreed to by the Parties;

(x) make any such decisions as are expressly allocated to the JRC under this Agreement; and

At the request of either Party's representatives to the JRC, conduct ad hoc meetings in addition to the quarterly meetings of the JRC as reasonably necessary to coordinate and expedite all decisions made by the JRC.

(d) Decision Making. The JRC shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on the JRC and leave decisions of the JRC to representatives of the other Party.

3.2 Alliance Management. Each of Sanofi and Regeneron shall appoint a senior representative who possesses a general understanding of research, clinical, and regulatory issues to act as its Alliance Manager ("Alliance Manager"). Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Alliance Manager will also be responsible for providing single-point communication for seeking consensus both internally within the respective Party's organization and with the other Party's organization, including facilitating review of external corporate communications.

3.3 Resolution of Governance Matters.

(a) Generally. The Parties shall cause their respective representatives on the JRC to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible.

(b) Executive Officers' Resolution of Disputes. In the event that the JRC is, after a period of thirty (30) days from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, or the Parties are unable to agree on the budget for the Initial Development Plan for a Product Candidate in accordance with Section 5.3 below, either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, the co-chairpersons of the JRC, by written notice to each Party delivered within five (5) days after receipt of the notice from a Party pursuant to the immediately preceding sentence, shall formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within thirty (30) days of receiving such written notification or such

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3283

Samsung Bioepis Exhibit 1017, pg. 3283

longer period of time as the Executive Officers may agree in writing. Regeneron's Executive Officer shall have the deciding vote over all matters referred to the Executive Officers by the JRC, other than matters related to the commercial reasonableness of the budget for the Initial Development Plan for a Product Candidate which shall be resolved in accordance with Section 13.1 below should the Executive Officers fail to resolve such matter.

3.4 Obligations of the Parties and their Affiliates. The Parties shall cause their respective designees on the JRC and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein.

ARTICLE 4
PAYMENTS

4.1 Upfront Payment. Within five (5) Business Days of the Effective Date, Sanofi will pay to Regeneron the non-refundable, non-creditable amount of US $85,000,000 (which will not be reduced by any withholding or similar taxes) as consideration for access to Regeneron's research capabilities and suite of discovery technologies and the co-exclusive (with Regeneron) rights granted to Sanofi hereunder during the term of the Discovery Program, including the Tail Period, if any.

4.2 Discovery Program Costs. Commencing on the Effective Date and continuing during the term of the Discovery Program, Sanofi shall be responsible for paying one hundred percent (100%) of all Discovery Program Costs, including Discovery Program Costs incurred for a Product Candidate until the anticipated IND filing date for such Product Candidate, regardless of whether Sanofi exercises its Opt-In Rights in accordance with Section 5.1; provided that, except as set forth below, the total annual Discovery Program Costs to be paid by Sanofi in each of the first five (5) years of the Discovery Program (the "Maximum Annual Discovery Program Costs") shall not exceed the following amounts (as calculated for each Contract Year):

Contract Year	Maximum Annual Discovery Program Costs
1	**********
2	*********
3	*********
4	*********
5	*********

In the event that the Discovery Program Costs incurred in any Contract Year are less than the Maximum Annual Discovery Program Costs for such Contract Year, the amount of such shortfall up to ten percent (10%) of the Maximum Annual Discovery Program Costs stated immediately above for each Contract Year may be carried over to the ensuing Contract Year and added to the Maximum Annual Discovery Program Costs for such ensuing Contract Year except for any such shortfall at the end of Contract Year 5, such that Regeneron's right to carry over any shortfall shall not be applicable into or during the Tail Period. At least sixty (60) days prior to the end of each Contract Year, Regeneron shall notify Sanofi if it reasonably believes that the total Discovery Program Costs for such Contract Year will be less than the Maximum Annual

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3284

Samsung Bioepis Exhibit 1017, pg. 3284

Discovery Program Costs for such Contract Year and whether Regeneron intends to apply such shortfall amount to the Discovery Program Costs for the ensuing Contract Year.

To the extent that Sanofi performs any activities under the Discovery Program, it shall do so at its sole cost and expense and such costs and expenses shall not be treated as Discovery Program Costs for purposes of calculating the Maximum Annual Discovery Program Costs unless the JRC expressly requests Sanofi to perform any such activities, in which case the mutually agreed upon costs directly related to such activities shall be included in the calculation of the Maximum Annual Discovery Program Costs. The Parties acknowledge that payments made by Sanofi pursuant to this Section 4.2 are being made as research and development expenses, as defined in the U.S. Internal Revenue Code Section 41, and agree that any and all credits or deductions to which either party may be entitled on account of research performed pursuant to such payments shall be allocated to Sanofi to the extent of such payments.

4.3 Reports and Discovery Program Cost Payments. Within forty-five (45) days following the end of each calendar quarter, Regeneron shall deliver electronically to Sanofi a written report setting forth in reasonable detail the Discovery Program Costs incurred by Regeneron in such calendar quarter along with an invoice therefore. Sanofi shall reimburse Regeneron for all undisputed Discovery Program Costs set forth in each report within thirty (30) days after its receipt thereof. Any disputed, unpaid Discovery Program Costs that are determined to be due and payable to Regeneron under this Agreement shall be paid with the Default Interest Rate.

4.4 Royalty Payments for Royalty Products(i) . If either Party, or its Affiliate or licensee successfully develops and commercializes a Royalty Product, then the commercializing Party shall pay to the non-commercializing Party, within sixty (60) days following the end of each calendar quarter, the following royalties on the aggregate Net Sales of such, respective Royalty Products during the Royalty Term: **********.

In the event that any Royalty Product requires a sub-license to Sanofi Patent Rights or Regeneron Patent Rights, as applicable, and such sub-license is granted under this Agreement, then any financial remuneration that the licensing Party is required to pay to a Third Party for its license from the Third Party shall be considered a pass-through cost to be borne by the Party developing and/or commercializing the Royalty Product.

4.5 Royalty Reporting. The royalties payable under Sections 4.4 (i), 4.4(iv), and 4.4(v) of this Agreement shall each be paid for the period of time, as determined on a Royalty Product-by-Royalty Product and country-by-country basis, commencing on the Effective Date and ending on the later to occur of (a) ********** and, if applicable, (b) the expiration of the last to expire Valid Claim of the Licensed Sanofi Target IP or Regeneron Target IP, as the case may be. The royalties payable under Sections 4.4 (ii), 4.4 (iii), and 4.4(vi) of this Agreement shall each be paid on a Royalty Product-by-Royalty Product and country-by-country basis, commencing on the Effective Date and ending on the expiration of the last to expire Valid Claim of the licensed Sanofi Target IP (the applicable period of time during which royalties are payable pursuant to this sentence and the preceding sentence being referred to as the applicable "Royalty Term"). During the applicable Royalty Term, the Party owing royalties shall deliver to

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3285

Samsung Bioepis Exhibit 1017, pg. 3285

the other Party with each royalty payment a report detailing in reasonable detail the information necessary to calculate the royalty payments due under this Agreement for such calendar quarter, including the following information, specified on a Royalty Product-by-Royalty Product and country-by-country basis: (a) total gross invoiced amount from sales of each Royalty Product by a Party, its Affiliates and sublicensees; (b) all relevant deductions from gross invoiced amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable.

4.6 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars using the average of the buying and selling exchange rate for conversion of the applicable foreign currency into United States Dollars, using the spot rates (the "Closing Mid-Point Rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties) from the last Business Day of the preceding month.

4.7 Late Payments. All late payments made under this Agreement (including payments made pursuant to Sections 4.4 and 4.5 above), shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (U.S., Eastern Edition) effective for the date on which the payment was due ********** (such sum being referred to as the "Default Interest Rate").

4.8 Taxes. Except as set forth in Section 4.1, any withholding or other taxes that a Party is required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to such other Party; provided, however, that the remitting Party shall furnish the other Party with proper evidence, including any self-reporting documentation, of the taxes so paid. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable).

ARTICLE 5
OPT-IN RIGHTS TO LICENSE PRODUCT CANDIDATES

5.1 Opt-In Rights to License Product Candidates. Subject to the last sentence of this Section 5.1 and the other terms of this Agreement, Sanofi shall have the exclusive right during the term of the Discovery Program to elect to jointly (with Regeneron) develop and commercialize each Product Candidate as set forth below, under the terms and conditions set forth in the License and Collaboration Agreement (the "Opt-In Rights"). While the Opt-In Rights are in effect with respect to an Antibody from the Discovery Program, including a MTC in the Discovery Program, Regeneron will not grant to any Third Party rights to any such Antibody. The Opt-In Rights will expire and Sanofi will no longer have any rights or licenses to any Antibodies, including MTCs, under this Agreement upon the expiration or earlier

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3286

Samsung Bioepis Exhibit 1017, pg. 3286

termination of the Discovery Program. After the first five (5) years of the Discovery Program (or if the Discovery Program is earlier terminated by Sanofi under the terms of Section 12.4), the Opt-In Rights shall remain in effect during the Tail Period solely with respect to Lead Candidates and other Antibodies and MTCs against any applicable Targets properly identified by Sanofi in its notice to extend the Discovery Program through the Tail Period provided under Section 2.9.

5.2 Process for Opt-In Rights. **********.

5.3 Initial Development Plan. Within thirty (30) days after Sanofi's receipt of the Opt-In Report, the Parties shall jointly commence, and thereafter as promptly as practicable complete, preparation of a plan and budget for the planned development activities for such Product Candidate through the completion of the Phase I Clinical Trial (the "Initial Development Plan"), the final budget included in which shall be subject to Sanofi's written approval, not to be unreasonably withheld or delayed; provided, however, that (i) the Parties shall not be required to continue or complete such preparation if the Opt-In Period for such Product Candidate has expired without Sanofi having timely exercised its Opt-In Rights with respect thereto or Sanofi shall have otherwise advised Regeneron in writing that it will not exercise its Opt-In Rights with respect to such Product Candidate and (ii) if the Parties are unable to agree on a final budget the matter shall first be referred to the Executive Officers in accordance with Section 3.3(b) above, and if such Executive Officers are unable to resolve such matter, it shall be submitted to binding arbitration to be conducted in accordance with Section 13.1 below. If Sanofi properly exercises its Opt-In Rights with respect to a Product Candidate, such Product Candidate shall be developed in accordance with the Initial Development Plan until the Parties agree to the "Global Development Plan" as such term is defined in the License and Collaboration Agreement.

5.4 Opt-In Exercise. Sanofi may exercise its Opt-In Rights under this Agreement and license a Product Candidate under the License and Collaboration Agreement by delivering to Regeneron a written notice of exercise in the form annexed hereto as Exhibit A (an "Opt-In Notice") on or before the later of (i) **********, ("the "Opt-In Period"), **********.

5.5 Dll4 and REGN-88. Sanofi exercised its Opt-In Rights to REGN-88 as of the Effective Date and shall be deemed to have exercised its Opt-In Right with respect to Delta-like ligand-4 (Dll4) MTCs as of the Effective Date. For clarification, development of the Delta-like ligand-4 (Dll4) MTCs shall be conducted under this Agreement until such time as an IND is filed.

5.6 Refused Candidates. If Sanofi does not provide Regeneron with an Opt-In Notice within the Opt-In Period with respect to a particular Product Candidate, or Sanofi notifies Regeneron that it will not exercise Opt-In Rights with respect to the Product Candidate, then the following shall apply:

(i) Refused Candidate. The Opt-In Rights shall expire with respect to that Product Candidate (a "Refused Candidate"). All licenses granted in Section 2.10 shall automatically expire with respect to each Product Candidate upon such Product Candidate becoming a Refused Candidate. Following such time as a Product Candidate becomes a Refused Candidate, except as set forth below, the applicable Target

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3287

Samsung Bioepis Exhibit 1017, pg. 3287

shall no longer be deemed a Program Target and shall be removed from the Target List and Sanofi shall no longer have any rights to any Antibodies, including MTCs, against such Target under this Agreement. Sanofi shall have a one-time right within four (4) weeks of the date a Product Candidate becomes a Refused Candidate to designate the Target for such Refused Candidate as one of its Sanofi Targets.

(ii) Regeneron Rights. Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any Refused Candidate without restriction outside the Discovery Program and this Agreement, unless the Refused Candidate is a Competing Refused Candidate, in which case, Section 2.8(b)(ii) shall apply. In addition, unless Sanofi has exercised its right under Section 5.6(i) to designate the applicable Target for a Refused Candidate as one of its Sanofi Targets, then Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any MTCs or other Antibodies against such Target and may practice and use any Regeneron Intellectual Property, including, without limitation, the Mice, in connection with such activities. If Sanofi has designated the applicable Target for the Refused Candidate as a Sanofi Target pursuant to Section 5.6(i), then all Antibodies (including MTCs) against such Target that were generated under the Discovery Program other than the Refused Candidate shall remain part of the Discovery Program.

(iii) Sanofi Rights. Neither Sanofi nor its Affiliates, either directly or through any Third Party, may develop or commercialize an Antibody that is against the Target of a Refused Candidate **********.

ARTICLE 6
NEWLY CREATED INVENTIONS

6.1 Ownership of Newly Created Intellectual Property.

(a) Each Party shall exclusively own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created solely by such Party, its employees, agents and consultants under the Discovery Program ("Sole Inventions"). Sole Inventions made solely by Sanofi, its employees, agents and consultants are referred to herein as "Sanofi Sole Inventions." Sole Inventions made solely by Regeneron, its employees, agents and consultants are referred to herein as "Regeneron Sole Inventions." The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder.

(b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Discovery Programs that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Sanofi (or for which ownership vests in Sanofi by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron (or for

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3288

Samsung Bioepis Exhibit 1017, pg. 3288

which ownership vests in Regeneron by operation of law), on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions").

(c) Notwithstanding the foregoing in Section 6.1(b), (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, as determined, if necessary, by an independent third party, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws, and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under this Agreement vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) The Parties hereby agree that each Party's use of the Joint Inventions shall be governed by the terms and conditions of this Agreement including the following: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement or the License and Collaboration Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as otherwise set forth herein or in the License and Collaboration Agreement, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 6.1(e), (iii) during the Discovery Program, each Party agrees not to license its interest in any Joint Invention with the right to use such Joint Invention for developing, manufacturing or commercializing antibodies (except for developing, manufacturing or commercializing a Party's Antibodies that may be included in the exclusions described in Section 2.8 (b) of the Agreement), and (iv) nothing in this Article 6 shall relieve a Party or its Affiliates of their obligations under Article 9 with respect to Confidential Information provided by the other Party or such other Party's Affiliates. Neither Party hereto shall have the obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Discovery Program. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. The provisions governing Joint Inventions set forth in this Section 6.1(e) shall survive the expiration or termination of this Agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3289

Samsung Bioepis Exhibit 1017, pg. 3289

6.2 Prosecution and Maintenance of Patent Rights.

(a) Subject to the terms of the License and Collaboration Agreement with respect to Licensed Products, Regeneron shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights and Regeneron shall confer with and keep Sanofi reasonably informed regarding the status of such activities to the extent they are Product Patent Rights. **********.

(b) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of Regeneron. Regeneron shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners **********.

(c) The Parties shall have the following obligations with respect to the filing, prosecution and maintenance of any Joint Patent Rights, as well as any Product Patent Rights: (i) the prosecuting Party (the "Prosecuting Party") shall provide the other Party (the "Non-Prosecuting Party") with notice and a copy of a substantially completed draft of any Patent Application at least thirty (30) days prior to the filing of any such Patent Application by the Prosecuting Party and incorporate all reasonable comments provided by the Non-Prosecuting Party within such thirty (30) day period unless the Prosecuting Party reasonably believes that such comments will adversely affect the scope or validity of the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) the Prosecuting Party shall notify the Non-Prosecuting Party prior to its filing of a Patent Application; (iii) the Prosecuting Party shall consult with the Non-Prosecuting Party promptly following the filing of the Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv) the Prosecuting Party shall provide the Non-Prosecuting Party promptly with copies of all material communications received from or filed in patent offices with respect to such applications and incorporate all reasonable comments provided by the Non-Prosecuting Party, unless the Prosecuting Party reasonably believes that such comments will adversely affect the validity or scope of the Patent Application or resulting Patent for both Parties; and (v) the Prosecuting Party shall provide the Non-Prosecuting Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office, (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the Non-Prosecuting Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances, including assuming the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right or Joint Patent Right and becoming the Prosecuting Party. With respect to Joint Inventions, it is understood that the Prosecuting Party and Non-Prosecuting Party shall use all reasonable efforts to reach agreement on all material filings and amendments and no such material filings or amendments shall be made by the Non-Prosecuting Party without the prior written agreement of

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3290

Samsung Bioepis Exhibit 1017, pg. 3290

the Non-Prosecuting Party, such agreement not to be unreasonably withheld or delayed. In addition, in the event that the Prosecuting Party materially breaches the foregoing obligations and such material breach is not cured within thirty (30) days of a written notice from the Non-Prosecuting Party describing such breach in reasonable detail, or in the event that the Prosecuting Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the Non-Prosecuting Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the Non-Prosecuting Party may assume the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right and will thereafter be deemed the Prosecuting Party for purposes hereof. Notwithstanding the foregoing, the Prosecuting Party may withdraw from or abandon any Patent or Patent Application on thirty (30) days' prior notice to the Non-Prosecuting Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the Non-Prosecuting Party a free-of-charge option to assume the prosecution or maintenance thereof. The Parties will file and prosecute Patent Applications described in this Section 6.2(a) in the list of countries set forth in Exhibit C, unless otherwise agreed upon by the Parties.

(d) All costs incurred in the filing, prosecution and maintenance of any Joint Patent Rights and Product Patent Rights and in performing freedom to operate analyses on Program Targets or Lead Candidates shall be shared equally by the Parties.

6.3 Third Party Claims. In the normal course of business, Regeneron shall carry out patent searches in relation to the Program Targets, Lead Candidates, and Product Candidates, as well as the technologies used to discover, develop and commercialize any of the foregoing, and will disclose, along with any analysis, to Sanofi's counsel any conflict or likely conflict of which Regeneron is aware with respect to the Patent Rights of any Third Party with respect to any such Program Targets, Lead Candidates and Product Candidates prior to selection to enter IND Preparation. If either Party or its Affiliates shall learn of a Third Party claim that the activities under the Discovery Program infringe or otherwise violate the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this claim, assertion or certification. As soon as reasonably practical after the receipt of such notice, the Parties shall cause their respective legal counsel to meet to confer on such allegation of infringement. In particular, with regard to issues related to freedom to operate concerning Targets pursued under this Agreement, the Parties shall conduct and maintain ongoing and regular communications between their legal/intellectual property departments.

ARTICLE 7
BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

7.1 Books and Records. Each Party shall keep proper books of record and account in which full, true and correct entries (in conformity with GAAP) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall permit auditors, as provided in Section 7.2, to visit and inspect, during regular business hours and under the guidance of its employees, the books of record and account of such Party to the extent relating to this Agreement and discuss its affairs, finances and accounts to the extent relating to this Agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3291

Samsung Bioepis Exhibit 1017, pg. 3291

7.2 Audits and Adjustments.

(a) Each Party shall have the right, upon no less than thirty (30) days' advance written notice and at such reasonable times and intervals and to such reasonable extent as the Party shall request, not more than once during any Contract Year, to have the books and records of the other Party to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable, appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days of delivery. If a Party over billed or underpaid an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than **********, it shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the Party initiating the audit in all other cases). Such accountants shall not reveal to the Party requesting the audit the details of its review, except for the findings of such review and such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article 9.

(c) If any examination or audit of the records described above discloses an over billing or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 7.2(b) above, the Party that overbilled or underpaid shall pay the same (plus interest thereon at the Default Interest Rate from the date of such over billing or underpayment through the date of payment of the amount required to be paid pursuant to this Section 7.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section 7.2.

(d) Disputes. Any disputes with respect to the results of any audit conducted under Section 7.2 above shall be resolved by binding arbitration in accordance with Section 13.1 below.

7.3 IAS/IFRS/GAAP. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with IAS/IFRS, and for the US, if desired, GAAP, as generally and consistently applied.

ARTICLE 8
REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Joint Representations and Warranties. Each Party hereto represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3292

Samsung Bioepis Exhibit 1017, pg. 3292

(c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other material agreement or arrangement, whether written or oral, by which it is bound or requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from performing the Discovery Program or granting the rights and/or licenses hereunder; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf.

8.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any court, arbitrator, or Governmental Authority that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the term of the Discovery Program, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

8.3 Additional Regeneron Representations, Warranties and Covenants. Regeneron additionally represents and warrants to Sanofi that, as of the Effective Date:

(a) Regeneron owns or has a valid license to all Regeneron Patent Rights in existence as of the Effective Date;

(b) Regeneron has the right and authority to grant the rights (including the Opt-In Rights) granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted, and will not grant during the term of this Agreement, any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;

(c) there is no pending litigation of which Regeneron has received notice or is otherwise aware that alleges that any of Regeneron's activities relating to the Mice or the Regeneron Intellectual Property have violated, or would violate, the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation);

(d) to Regeneron's knowledge, no litigation has been otherwise threatened which alleges that any of its activities relating to the Mice or the Regeneron Intellectual Property have violated or would violate, any intellectual property rights of any Third Party;

(e) to Regeneron's knowledge, after due inquiry, the use of the Mice and the Regeneron Intellectual Property generally in the Discovery Program (but not with respect to a specific MTC or Target) does not and will not infringe or otherwise violate any valid Patent or provisional rights to applications or other intellectual property of any Third Party claiming genetically modified mice or the use thereof to make antibodies;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3293

Samsung Bioepis Exhibit 1017, pg. 3293

(f) neither the development or reproduction of the Mice nor the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Effective Date has constituted or involved the misappropriation of trade secrets or other rights of any Person;

(g) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Effective Date are not invalid or unenforceable, in whole or part;

(h) Regeneron has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings;

(i) The commercial terms of the "Mouse Purchase Agreement" referred to in Section 2.15 and as outlined in Exhibit B hereto are consistent with those contained in Regeneron's existing agreements with other commercial entities, and

(j) neither Regeneron nor any of its Affiliates shall transfer ownership, assign ownership, grant a security interest in or otherwise encumber any of its rights in, to or under any Regeneron Intellectual Property in a way that will impair Sanofi's rights or Regeneron ability to perform its obligations under this Agreement.

**********.

8.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 9
CONFIDENTIALITY

9.1 Confidential Information. During the term of this Agreement and for a period of five (5) years thereafter, each Party (in such capacity, the "Receiving Party") shall keep confidential, and other than as provided herein or in the License and Collaboration Agreement, shall not use or disclose, directly or indirectly, any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, documents, ideas, information, discoveries, or materials, owned, developed, or possessed by the other Party (in such capacity, the "Disclosing Party"), whether in tangible or intangible form, the confidentiality of which the Disclosing Party takes reasonable measures to protect, including but not limited to Regeneron Know-How and Sanofi Know-How disclosed by the Disclosing Party under this

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3294

Samsung Bioepis Exhibit 1017, pg. 3294

Agreement (the "Confidential Information"). For purposes of this Agreement, all confidential information disclosed by Regeneron under the terms of the confidentiality agreements between Sanofi Parent and Regeneron dated February 1, 2007 and October 23, 2007 is hereby deemed Confidential Information of Regeneron. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any Confidential Information of the other Party to any Third Party except to its employees, agents, consultants or any other Person under its authorization; provided such employees, agents, consultants or other Persons are subject in writing to confidentiality obligations applicable to the Disclosing Party's Confidential Information no less strict than those set forth herein.

(a) Notwithstanding the foregoing, Confidential Information shall not be deemed to include information and materials (and such information and materials shall not be considered Confidential Information under this Agreement) to the extent that it can be established by written documentation by the Receiving Party that such information or material is: (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the Receiving Party or any Person to whom the Receiving Party provided such information; (ii) is or was already in the possession of the Receiving Party at the time of disclosure by the Disclosing Party; (iii) is disclosed to the Receiving Party on an unrestricted basis from a Third Party not under an obligation of confidentiality to the Disclosing Party or any Affiliate of the Disclosing Party with respect to such information; (iv) information that has been independently created by the Receiving Party (or its Affiliate), as evidenced by written or electronic documentation, without any aid, application or use of the Disclosing Party's Confidential Information; or (v) required by Law to be disclosed, provided that the Receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the Disclosing Party to seek confidential treatment for such information, and provided further that the Receiving Party provides all reasonable cooperation to assist the Disclosing Party to protect such information and limits the disclosure to that information which is required by Law to be disclosed.

(b) Information and other Know-How that is discovered by Regeneron in connection with the Discovery Program will be considered Regeneron's Confidential Information, except to the extent it relates to a Licensed Product, in which case it shall be Confidential Information of both Parties, subject to the terms of the License and Collaboration Agreement.

(c) Specific aspects or details of Confidential Information will not be deemed to be within the public knowledge or in the prior possession of a Person merely because such aspects or details of the Confidential Information are embraced by general disclosures in the public domain. In addition, any combination of Confidential Information will not be considered in the public knowledge or in the prior possession of either Person merely because individual elements thereof are in the public domain or in the prior possession of a Person unless (i) the combination and its principles are in the public knowledge or in the prior possession of that Person and (ii) the combination is documented, in a single contemporaneous document, as in the public knowledge or in the prior possession of a Person.

(d) Notwithstanding anything else in this Agreement to the contrary, each Party hereto (and each employee, representative, or other agent of any Party) may disclose to any and all Persons, without limitation of any kind, the Federal income tax treatment and Federal

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3295

Samsung Bioepis Exhibit 1017, pg. 3295

income tax structure of any and all transaction(s) contemplated herein and all materials of any kind (including opinions or other tax analyses) that are or have been provided to any Party (or to any employee, representative, or other agent of any party) relating to such tax treatment or tax structure, provided, however, that this authorization of disclosure shall not apply to restrictions reasonably necessary to comply with securities laws. This authorization of disclosure is retroactively effective immediately upon commencement of the first discussions regarding the transactions contemplated herein, and the Parties aver and affirm that this tax disclosure authorization has been given on a date which is no later than thirty (30) days from the first day that any Party hereto (or any employee, representative, or other agent of any party hereto) first made or provided a statement as to the potential tax consequences that may result from the transactions contemplated hereby.

9.2 Injunctive Relief. The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

9.3 Publications. If either Sanofi or Regeneron (the "Publishing Party") desires to publish or publicly present any results from the Discovery Program in scientific journals, publications or scientific presentations or otherwise, the Publishing Party shall provide the other Party an advance final copy of any proposed publication or summary of a proposed oral presentation relating to the information from the Discovery Program prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to preserve the confidentiality of its Confidential Information and to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it as a result of the publication or disclosure, to which the Publishing Party shall give due consideration. If such other Party informs the Publishing Party, within thirty (30) days of receipt (or such other period agreed to by the JRC) of an advance copy of a proposed publication or summary of a proposed oral presentation, that such publication in its reasonable judgment should not be published or presented, the Publishing Party shall delay or prevent such disclosure or publication as proposed by the other Party. In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a patent application(s) or application(s) for a certificate of invention on the information involved. The Parties shall establish a publication review process to ensure compliance with this Section 9.3.

9.4 Disclosures Concerning this Agreement. The Parties will mutually agree upon the contents of a their respective press releases with respect to the execution of this Agreement and

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3296

Samsung Bioepis Exhibit 1017, pg. 3296

the License and Collaboration Agreement which shall be issued simultaneously by both Parties on the Effective Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or any other activities contemplated hereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement or any activities contemplated hereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding this Agreement. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article 9 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. Each Party acknowledges that the other Party as a publicly traded company is legally obligated to make timely disclosures of all material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall cooperate with one another and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE 10
INDEMNITY

10.1 Indemnity and Insurance.

(a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines and expenses, including reasonable attorneys' fees and costs (collectively, "Damages"), arising from or occurring as a

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3297

Samsung Bioepis Exhibit 1017, pg. 3297

result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:

(i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Sanofi or its Affiliates in connection with the Discovery Program, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Regeneron or its Affiliates; or

(ii) material breach by Sanofi of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

(b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and their respective officers, directors, employees and agents ("Sanofi Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Sanofi Indemnitee that is due to or based upon:

(i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Regeneron or its Affiliates in connection with the Discovery Program, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Sanofi or its Affiliates; or

(ii) material breach by Regeneron of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

10.2 Indemnity Procedure.

(a) The Party entitled to indemnification under this Article 10 (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened in writing against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder.

(i) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3298

Samsung Bioepis Exhibit 1017, pg. 3298

Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

(ii) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 10.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.

(iii) The amount of any Damages for which indemnification is provided under this Article 10 will be reduced by the insurance proceeds received, and any other amount recovered, if any, by the Indemnified Party in respect of any Damages.

(iv) If an Indemnified Party receives an indemnification payment pursuant to this Article 10 and subsequently receives insurance proceeds from its insurer with respect to the damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article 10 and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article 10.

ARTICLE 11
FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions, or acts of God ("Force Majeure"). Such excuse from liability and responsibility

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3299

Samsung Bioepis Exhibit 1017, pg. 3299

shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. The "Term" of this Agreement shall commence on the Effective Date and end on the later to occur of (a) the expiration or earlier termination of the Discovery Program, including any Tail Period, unless this Agreement is earlier terminated in accordance with this Article 12 in which event the Term shall end on the effective date of such termination.

12.2 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 12.2, this Agreement shall be terminable by a Party in its entirety if the other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period. Notwithstanding the foregoing, in the case of breach of a payment obligation not subject to a bona fide dispute hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be forty-five (45) days. For purposes of this Section 12.2, the term "material breach" shall mean an intentional, continuing (and uncured within the time period described above), material breach by a Party as determined by binding arbitration consistent with the provisions of Section 13.1 of this Agreement.

12.3 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or (b) if the other Party proposes a written agreement of composition or extension of its debts, or (c) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or (d) if the other Party shall propose or be a party to any dissolution or liquidation, or (e) if the other Party shall make an assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(52) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any Patent Rights in any country of a Party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code subject to

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3300

Samsung Bioepis Exhibit 1017, pg. 3300

the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

12.4 Termination by Sanofi on Notice. **********.

12.5 Termination for Breach of Standstill. Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have breached their obligations under any of Sections 3, 4 or 5 of the Investor Agreement (to the extent such sections of the Investor Agreement is then in effect). Furthermore, Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have (a) breached their obligations under Section 20.16 of the Aventis Collaboration Agreement, to the extent that such Section 20.16 remains in effect after the Effective Date, or (b) breached its obligations under Section 5.3 of the Stock Purchase Agreement, dated as of September 5, 2003, by and between Sanofi and Regeneron (the "Aventis Stock Purchase Agreement"), to the extent that such Section 5.3 remains in effect after the Effective Date. Any such breach of the Investor Agreement, the Aventis Stock Purchase Agreement or the Aventis Collaboration Agreement, as the case may be, shall be treated as a breach of this Agreement. Notwithstanding the foregoing and for the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of (i) a de minimus breach of Section 3.1(a) of the Investor Agreement (to the extent such Section 3.1(a) is in effect after the Effective Date) or of Section 20.16(a) of the Aventis Collaboration Agreement (to the extent such Section 20.16(a) remains in effect after the Effective Date) or (ii) an inadvertent breach of Section 3.1(g) of the Investor Agreement (to the extent such Section 3.1(g) is in effect after the Effective Date) or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement (to the extent such Section 20.16(g) remains in effect after the Effective Date), arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of such Section 20.16 or of paragraphs (a) through (e) of Section 3.1 of the Investor Agreement, as applicable. Sanofi's rights under Sections 2.16 and 2.17 shall survive termination for breach of the standstill or lock-up under Section 12.5 of the Agreement

12.6 Termination for Breach of License and Collaboration Agreement. Notwithstanding anything to the contrary herein, (a) Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Sanofi, if Regeneron has terminated the License and Collaboration Agreement, in its entirety, pursuant to Section 19.3, 19.4, or 19.5 of the License and Collaboration Agreement, and (b) Sanofi shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Regeneron, if Sanofi has terminated the License and Collaboration Agreement, in its entirety, pursuant to Section 19.3 or 19.4 of the License and Collaboration Agreement.

12.7 Effect of Termination by Sanofi for Breach. In addition to the provisions of Section 12.9 below, notwithstanding anything herein to the contrary, in the event that Sanofi terminates this Agreement pursuant to Section 12.2 of this Agreement the following shall apply:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3301

Samsung Bioepis Exhibit 1017, pg. 3301

(a) Sanofi shall be granted a non-exclusive, non-transferable, royalty free, worldwide license, without the right to sublicense, for a period that shall expire six (6) years from the Effective Date, to the Mice and the underlying Regeneron Intellectual Property for Sanofi and its Affiliates to use to discover and develop MTCs for any and all purposes;

(b) Regeneron shall perform a timely and expeditious technology transfer as required by Sanofi to pursue its rights under subsection (a) without delay above subject to the execution of a material transfer agreement containing non-financial terms and conditions related to the use of the Mice consistent with Regeneron's commercial license agreements for the Mice;

(c) the licenses granted to Regeneron under this Agreement shall automatically terminate;

(d) Sanofi shall be granted an exclusive, fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense, under Regeneron Target IP existing at the effective time of termination solely for use to develop and commercialize Antibodies against Sanofi Discovery Targets (and for no other uses), and the co-exclusive (with Regeneron and its Affiliates) fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense under Regeneron Target IP to develop and commercialize Antibodies against all other Program Targets at the time of termination (and for no other uses); and

(e) Sanofi's rights under Sections 2.15, 2.16 and 2.17 shall survive; and

(f) Sanofi shall have no further funding obligations under Section 4.2 of the Agreement.

12.8 Effect of Termination by Regeneron for Breach. In addition to the provisions of Sections 12.9 and 12.11 below, notwithstanding anything herein to the contrary, in the event that Regeneron terminates this Agreement pursuant to Section 12.2 or 12.5 of this Agreement, the following shall apply:

(a) the licenses granted to Sanofi under this Agreement shall automatically terminate;

(b) the rights granted to Sanofi under this Agreement in Sections 2.15, 2.16, and 2.17 and Article 5 shall automatically terminate;

(c) Regeneron shall be granted an exclusive, fully paid-up, non-transferable, royalty-free, worldwide, exclusive license, with the right to sublicense, under Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize Antibodies against Program Targets other than Sanofi Discovery Targets (and for no other uses), and the co-exclusive (with Sanofi and its Affiliates) fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense under Sanofi Target IP to develop and commercialize Antibodies against all Sanofi Discovery Targets at the time of termination (and for no other uses).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3302

Samsung Bioepis Exhibit 1017, pg. 3302

12.9 Survival of Obligations. Subject to Sections 12.7 and 12.8 above and except as otherwise provided below, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate, and this Agreement shall cease to be of further force or effect, provided that notwithstanding any expiration or termination of this Agreement:

(a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of the Discovery Program (even if such costs and expenses arise following termination or expiration, as the case may be); provided, however, that Sanofi shall not be obligated to pay or reimburse Regeneron for any such costs or expenses in the event Sanofi terminates this Agreement pursuant to Section 12.2 above (and with respect to 12.4, Sanofi shall have no further obligations to pay for costs and expenses beyond the effective date of its termination notice);

(b) the obligations of the Parties with respect to the protection and nondisclosure of the other Party's Confidential Information in accordance with Article 9, as well as other provisions (including, without limitation, Sections 2.11(b), 2.11(c), 2.12 (except as set forth in Section 12.8 above), 2.13 (except as set forth in Section 12.8 above), 2.16, 2.17, 6.1(e), 6.2(b), 6.2(c), 6.2(d)(as it relates to Joint Patent Rights), 7.2, 10.1, 10.2, this Article 12, and Article 13) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable;

(c) for the avoidance of doubt, the early termination of this Agreement by either Party, and the expiration of this Agreement shall not relieve either Party of any of its royalty or other obligations under Article 4 with respect to any Royalty Product, for which royalties remain payable to the other Party under this Agreement; and such royalty provisions of Article 4 shall survive;

(d) for the avoidance of doubt, the obligations of the Parties with respect to the licenses granted in Sections 2.10, 2.11 (b), 2.11(c), 2.12, 2.13 shall survive the termination or expiration of this Agreement; and

(e) such expiration or termination and this Article 12 shall be without prejudice to any rights or remedies a Party may have for breach of this Agreement.

12.10 Return of Confidential Information. Subject to either Parties' licenses that survive termination or expiration, Confidential Information disclosed by the Disclosing Party, including permitted copies, shall remain the property of the Disclosing Party. Subject to the terms of the License and Collaboration Agreement (with respect to Licensed Products), upon the earlier to occur of (a) the termination of this Agreement or (b) the expiration of the Discovery Program, or upon written request of the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or, at the Disclosing Party's request, destroy, all documents or other tangible materials representing the Disclosing Party's Confidential Information (or any designated portion thereof); provided that one (1) copy may be maintained in the confidential files of the Receiving Party for the purpose of complying with the terms of this Agreement. An officer of the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3303

Samsung Bioepis Exhibit 1017, pg. 3303

Receiving Party also shall certify in writing that it has satisfied its obligations under this Section 12.10 within ten (10) days of a written request by the Disclosing Party.

12.11 Special Damages. If Regeneron terminates this Agreement pursuant to Section 12.2 or 12.5, then Sanofi shall pay to Regeneron, within sixty (60) days of the termination of this Agreement, in addition to any other amount payable by Sanofi to Regeneron under this Agreement under Laws, or pursuant to any contractual remedies available to Regeneron, an amount equal to the sum of the Maximum Annual Discovery Program Costs for each of the years, including the remaining unpaid Maximum Annual Discovery Program Cost for the Contract Year in which such termination is effective, that would have been the remainder of the term of the Discovery Program but for the termination of this Agreement.

12.12 Termination by Sanofi At Will. Sanofi shall be entitled to terminate this Agreement at any time (except following a material breach of this Agreement by Sanofi pursuant to Section 12.2) without cause upon three months' written notice to Regeneron. If Sanofi terminates the Agreement under this Section 12.12, then Sanofi shall pay to Regeneron within five (5) days of its notice of termination, an amount equal to the sum of the Maximum Annual Discovery Program Costs for each of the years, including the Remaining Unpaid Maximum Annual Discovery Program Cost for the Contract Year in which such termination is effective, that would have been the remainder of the term of the Discovery Program but for the termination of this Agreement. In addition, Sanofi shall complete GLP toxicology studies conducted by Sanofi at the time of termination, if applicable, and such other critical activities conducted by Sanofi at the time of termination that cannot be transferred to Regeneron without a material adverse effect on the completion of such activities. In the event of such termination, in addition to the provisions of Section 12.9, the following shall apply:

(a) the rights granted to Sanofi under Sections 2.16, and 2.17 and Article 5 shall automatically terminate; and

(b) Regeneron shall be granted a non-exclusive, non-transferable, royalty bearing (in accordance with Section 4.4) worldwide license with the right to sublicense under Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize (i) MTCs against Program Targets, and (ii) any other Antibodies against Program Targets in the Discovery Program in existence at the effective time of termination of this Agreement.

ARTICLE 13
ARBITRATION

13.1 Binding Arbitration. In the event the Parties cannot reach agreement with respect to (i) the commercial reasonableness of the budget for the Initial Development Plan for a Product Candidate, (ii) the royalty on Net Sales of Immunoconjugates under Section 2.11(d)(i) and (iii) of this Agreement, (iii) whether a breach constitutes a "material breach" as described in Section 12.2 of this Agreement, and (iv) audits under Section 7.2 (d) above, and such disputes are not resolved by the Executive Officers in accordance with Section 3.3(b) above, then the following shall apply:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3304

Samsung Bioepis Exhibit 1017, pg. 3304

(a) General. The respective disputed issue shall be referred to binding arbitration by one (1) arbitrator who shall be an independent expert in the pharmaceutical or biotechnology industry mutually acceptable to the Parties. The Parties shall use their best efforts to mutually agree upon one (1) arbitrator; provided, however, that if the Parties have not done so within ten (10) days after initiation of arbitration hereunder, or such longer period of time as the Parties have agreed to in writing, then such arbitrator shall be an independent expert as described in the preceding sentence selected by the New York office of the American Arbitration Association. Such arbitration shall be limited to casting the deciding vote with respect to the disputed issues as more fully described in Sections 13.1 (b)-(e) below. In connection therewith, each Party shall submit to the arbitrator in writing its position on and desired resolution of such matter. Such submission shall be made within ten (10) days of the selection or appointment of the arbitrator, and the arbitrator shall rule on such matter within ten (10) days of receipt of the written submissions by both Parties. The arbitrator shall select one of the Party's positions as his or her decision, and shall not have authority to render any substantive decision other than to so select the position of either Regeneron or Sanofi. Except as provided in the preceding sentence, such arbitration shall be conducted in accordance with the then-current Commercial Arbitration Rules of the American Arbitration Association. The arbitrator's ruling shall be final and binding upon the Parties. The costs of any arbitration conducted pursuant to this Section 13.1 shall be borne equally by the Parties. The Parties shall use diligent efforts to cause the completion of any such arbitration within sixty (60) days following a request by any Party for such arbitration.

(b) Initial Development Plan Budget. The specific issue that shall be submitted to the arbitrator shall be limited to determining the overall commercial reasonableness of the budget that is the subject of the dispute. If the arbitrator determines that such budget is commercially reasonable, then the dispute shall be deemed finally resolved and such resolution shall be binding on the Parties. However, if the arbitrator determines that such budget is not commercially reasonable, then the arbitrator shall, within fifteen (15) days after such determination, render a final decision as to what modifications must be made to such budget in order for it to be commercially reasonable (the "Budget Modification Decision"). In connection with reaching a Budget Modification Decision, the arbitrator may order the Parties to produce any documents or other information which are relevant to such final decision, and the Parties shall submit such documents or other information, together with their respective proposed resolutions which shall consist of their respective proposed modifications to the budget in order for it to be commercially reasonable, at least five (5) days prior to the date a Budget Modification Decision is required to be rendered as provided above. In rendering the final decision, the arbitrator shall be limited to choosing a resolution proposed by a Party without modification.

(c) Royalty on Net Sales **********: The issue that shall be submitted to the arbitrator shall be the royalty rate to apply under Section 2.11(d)(i).

(d) Material Breach Under Section 12.2: The issue that shall be submitted to the arbitrator shall be whether the breach committed by a Party meets the requirements for a material breach under Section 12.2 of this Agreement.

(e) Audit Disputes. The issue that shall be submitted to the arbitrator shall be disputes as described under Section 7.2(d) of this Agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3305

Samsung Bioepis Exhibit 1017, pg. 3305

ARTICLE 14
MISCELLANEOUS

14.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Except as set forth in Article 13 and 7.2(d), the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

14.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

14.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 14.3 attached hereto and shall be (a) delivered personally, (b) sent via a reputable nationwide overnight courier service, or (c) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, one (2) Business Days after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.

14.4 Entire Agreement. This Agreement and the License and Collaboration Agreement contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersede all prior understandings and writings relating to the subject matter hereof and thereof. It is understood and agreed that in the event of any conflict or inconsistency between this Agreement and the License and Collaboration Agreement, this Agreement shall control regarding the Parties' rights and obligations with respect to any Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program (prior to Sanofi's exercise of its Opt-In Rights with respect to such Product Candidate), and the License and Collaboration Agreement shall control regarding the Parties' rights and obligations with respect to any Licensed Product from and after the time a Product Candidate becomes a Licensed Product.

14.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3306

Samsung Bioepis Exhibit 1017, pg. 3306

14.6 Interpretation. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) the words "herein" or "hereunder" relate to this Agreement. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP, but only to the extent consistent with its usage and the other definitions in this Agreement.

14.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

14.8 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any Third Party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

14.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of Section 14.12 below.

14.10 Affiliates. Each Party may carry out its obligations under this Agreement through its Affiliates and absolutely, unconditionally and irrevocably guarantees to the other Party prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. Sanofi shall not, directly or indirectly, cause or direct Sanofi Pasteur or Merial Limited to take any action for which Sanofi and its Affiliates are prohibited hereunder from committing. Each Party represents and warrants to the other Party that it has licensed or

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3307

Samsung Bioepis Exhibit 1017, pg. 3307

will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

14.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

14.12 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Article 10 is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

14.13 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

14.14 Limitation of Damages. EXCEPT AS SET FORTH IN SECTION 12.11, IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 14.14 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD PARTY CLAIMS .

14.15 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the performance of the Discovery Program to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3308

Samsung Bioepis Exhibit 1017, pg. 3308

14.16 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.

[Remainder of page intentionally left blank; signature page follows]

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3309

Samsung Bioepis Exhibit 1017, pg. 3309

IN WITNESS WHEREOF, Sanofi and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMACEUTICALS INC.

By /s/ Karen Linehan
Name: Karen Linehan
Title: Authorized Signatory

By /s/ Robin White
Name: Robin White
Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By /s/ Leonard Schleifer
Name: Leonard Schleifer
Title: President & CEO

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3310

Samsung Bioepis Exhibit 1017, pg. 3310

Exhibit 10.18

SCHEDULE 1.19

Excluded Candidates

Regeneron's Excluded Candidates

****

Sanofi's Excluded Candidates

****

Exhibit 10.18

SCHEDULE 1.42

Lead Candidate Criteria

**********.

Exhibit 10.18

SCHEDULE 1.46

Manufacturing Cost

**********.

Exhibit 10.18

SCHEDULE 1.94

Form of Target List

****

Exhibit 10.18

Schedule 4.4

****

Exhibit 10.18

SCHEDULE 8.3

****

Exhibit 10.18

SCHEDULE 14.3

Notices

If to Sanofi:

Aventis Pharmaceuticals Inc.
200 Crossing Boulevard
Bridgewater, New Jersey 08807
United States
Attn: President US Research and Development

Copy: Sanofi Aventis
174 Avenue de France
75013 Paris
France
Attn: Senior Vice President and General Counsel

If to Regeneron:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: President & CEO
Copy: General Counsel

Exhibit 10.18

EXHIBIT A

Form of Opt-In Notice

[Sanofi Letterhead]

[DATE]

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: President & CEO
Copy: General Counsel Regeneron Pharmaceuticals, Inc.

Reference is hereby made to the Discovery and Preclinical Development Agreement (the "Discovery Agreement") by and between Aventis Pharmaceuticals Inc., a [ ], corporation with a principal place of business located at [ ], and Regeneron Pharmaceuticals, Inc., a New York corporation with a principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Capitalized terms used herein shall have the defined meanings set forth in the Discovery Agreement.

Pursuant to Section 5.4 of the Discovery Agreement, Sanofi hereby provides this Opt-In Notice to Regeneron to license [INSERT PRODUCT CANDIDATE] under the License and Collaboration Agreement. Effective immediately, [INSERT PRODUCT CANDIDATE] shall be considered a Licensed Product.

AVENTIS PHARMACEUTICALS INC.

_____

Name:
Title:

Exhibit 10.18

EXHIBIT B

****

Exhibit 10.18

EXHIBIT C

****

Exhibit 10.19

Portions of this Exhibit Have Been
Omitted and Separately Filed with the Securities
And Exchange Commission with a Request
For Confidential Treatment

LICENSE AND COLLABORATION AGREEMENT

By and Among

AVENTIS PHARMACEUTICALS INC.,

SANOFI-AVENTIS AMERIQUE DU NORD

and

REGENERON PHARMACEUTICALS, INC.

Dated as of November 28, 2007

TABLE OF CONTENTS

		Page
ARTICLE I DEFINITIONS		1
1.1	"Additional Major Market Country"	1
1.2	"Affiliate"	2
1.3	"Ancillary Agreements"	2
1.4	"Anticipated First Commercial Sale"	2
1.5	"Approval"	2
1.6	"Aventis LLC"	2
1.7	"Aventis Collaboration Agreement"	2
1.8	"Aventis Stock Purchase Agreement"	3
1.9	"BLA"	3
1.10	"Business Day"	3
1.11	"Clinical Supply Cost"	3
1.12	"Clinical Supply Requirements"	3
1.13	"Co-Commercialize" or "Co-Commercialization"	3
1.14	"Co-Commercialization Country"	3
1.15	"COGS"	4
1.16	"Commercial Overhead Charge"	4
1.17	"Commercial Supply Cost"	4
1.18	"Commercial Supply Requirements"	4
1.19	"Commercialize" or "Commercialization"	4
1.20	"Commercially Reasonable Efforts"	4
1.21	"Committee"	5
1.22	"Competing Opt-Out Product"	5
1.23	"Competing Product"	5
1.24	"Confidentiality Agreements"	5
1.25	"Consolidated Payment Report"	5
1.26	"Contract Sales Force"	5
1.27	"Contract Year"	5
1.28	"Controlling Party"	5
1.29	"Co-Promote" or "Co-Promotion"	5
1.30	"Country/Region Commercialization Budget"	5
1.31	"Country/Region Commercialization Plan"	5
1.32	"Country/Region Commercialization Committee", or "CRCC"	6
1.33	"Detail"	6
1.34	"Develop" or "Development"	6
1.35	"Development Costs"	6
1.36	"Development FTE Cost"	7
1.37	"Development FTE Rate"	7
1.38	"Development Plan"	7
1.39	"Discovery Program"	7
1.40	"EMEA"	7

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3322

Samsung Bioepis Exhibit 1017, pg. 3322

		Page
1.41	"Executive Officers"	8
1.42	"FDA"	8
1.43	"Field"	8
1.44	"Finished Product"	8
1.45	"First Commercial Sale"	8
1.46	"Formulated Bulk Product"	8
1.47	"FTE"	8
1.48	"GAAP"	8
1.49	"Global Commercialization Budget"	8
1.50	"Global Commercialization Plan"	8
1.51	"Global Development Budget"	8
1.52	"Global Development Plan"	9
1.53	"Good Practices"	9
1.54	"Governmental Authority"	9
1.55	"IAS/IFRS"	9
1.56	"ICH"	9
1.57	"IND"	9
1.58	"Indication"	9
1.59	"Initial Development Plan"	9
1.60	"Initial IND Filing Date"	9
1.61	"Investor Agreement"	9
1.62	"Joint Patent Rights"	9
1.63	"Know-How"	9
1.64	"Law" or "Laws"	10
1.65	"Lead Regulatory Party"	10
1.66	"Legal Dispute"	10
1.67	"License"	10
1.68	"Licensed Products"	10
1.69	"Major Market Country"	10
1.70	"Manufacture" or "Manufacturing"	10
1.71	"Marketing Approval"	10
1.72	"Manufacturing Plan"	10
1.73	"Medical Post-Approval Cost"	10
1.74	"Medical Post-Approval FTE Rate"	11
1.75	"Net Sales"	11
1.76	"New Information"	12
1.77	"Non-Approval Trials"	12
1.78	"Opt-In Right"	12
1.79	"Opt-Out Product"	12
1.80	"Other Shared Expenses"	12
1.81	"Out-of-Pocket Costs"	13
1.82	"Party Information"	13
1.83	"Patent Application"	13
1.84	"Patent Rights"	13
1.85	"Patents"	13
1.86	"Person"	13

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3323

Samsung Bioepis Exhibit 1017, pg. 3323

		Page
1.87	"Phase 3 Trial"	13
1.88	"Plan"	13
1.89	"Positive Phase 3 Trial Results"	13
1.90	"Pre-Launch Marketing Expenses"	13
1.91	"Pricing Approval"	14
1.92	"Product Candidate"	14
1.93	"Product Trademark"	14
1.94	"Promotional Materials"	14
1.95	"Quarter" or "Quarterly"	14
1.96	"Regeneron Intellectual Property"	14
1.97	"Regeneron Know-How"	14
1.98	"Regeneron Patent Rights"	14
1.99	"Region"	14
1.100	"Registration Filing"	15
1.101	"Regulatory Authority"	15
1.102	"Reporting Country/Region"	15
1.103	"Rest of World" or "ROW"	15
1.104	"Rest of World Country"	15
1.105	"ROW CPI"	15
1.106	"Sales Force Cost"	15
1.107	"Sales Force FTE Rate"	15
1.108	"Sanofi Intellectual Property"	16
1.109	"Sanofi Know-How"	16
1.110	"Sanofi Patent Rights"	16
1.111	"Sanofi Stock Purchase Agreement"	16
1.112	"Shared Commercial Expenses"	16
1.113	"Shared Phase 3 Trial Costs"	17
1.114	"Sublicensee"	17
1.115	"Target"	18
1.116	"Terminated Licensed Product"	18
1.117	"Termination Notice Period"	18
1.118	"Territory"	18
1.119	"Third Party"	18
1.120	"United States," "US" or "U.S."	18
1.121	"US CPI"	18
1.122	"Valid Claim"	18
1.123	Additional Definitions	18
ARTICLE II COLLABORATION		20
2.1	Scope of Collaboration	20
2.2	Compliance With Law	21
2.3	Further Assurances and Transaction Approvals	21
2.4	Compliance with Third Party Agreements	21
2.5	Plans	21
2.6	Limitation on Exercise of Rights Outside of Collaboration	21

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3324

Samsung Bioepis Exhibit 1017, pg. 3324

		Page
ARTICLE III MANAGEMENT		26
3.1	Committees/Management	26
3.2	Joint Steering Committee	27
3.3	Joint Development Committee	28
3.4	Joint Commercialization Committee	29
3.5	Country/Region Commercialization Committees	31
3.6	Joint Finance Committee	31
3.7	Joint Manufacturing Committee	31
3.8	Membership	31
3.9	Meetings	32
3.10	Decision-Making	32
3.11	Resolution of Governance Matters	32
ARTICLE IV LICENSE GRANTS		33
4.1	Regeneron License Grants	33
4.2	Sanofi License Grants	33
4.3	Newly Created Intellectual Property	34
4.4	Sublicensing	34
4.5	No Implied License	35
4.6	Retained Rights	35
ARTICLE V DEVELOPMENT ACTIVITIES		35
5.1	Development of Licensed Products	35
5.2	Global Development Plans	35
5.3	Global Development Budgets	36
5.4	Development Reports	36
5.5	Review of Clinical Trial Protocols	37
5.6	Regeneron Early Development Opt-Out	37
ARTICLE VI COMMERCIALIZATION		38
6.1	Commercialization of Licensed Products in the Field in the Territory	38
6.2	Global Commercialization Plan(s)	38
6.3	Country/Region Commercialization Plans	39
6.4	Commercialization Efforts; Sharing of Commercial Information	39
6.5	Co-Commercialization of Licensed Products	40
6.6	Licensed Product Pricing and Pricing Approvals in the Territory	42
6.7	Sales and Licensed Product Distribution in the Territory; Other Responsibilities	42
6.8	Contract Sales Force	43
6.9	Promotional Materials	43
6.10	Promotional Claims/Compliance	44
6.11	Restriction on Bundling in the Territory	44
6.12	Inventory Management	44
6.13	Medical and Consumer Inquiries	44
6.14	Market Exclusivity Extensions	44
6.15	Post Marketing Clinical Trials	44

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3325

Samsung Bioepis Exhibit 1017, pg. 3325

		Page
ARTICLE VII CLINICAL AND REGULATORY AFFAIRS		44
7.1	Ownership of Approvals and Registration Filings	44
7.2	Regulatory Coordination	45
7.3	Regulatory Events	46
7.4	Pharmacovigilance and Product Complaints	47
7.5	Regulatory Inspection or Audit	47
7.6	Recalls and Other Corrective Actions	47
ARTICLE VIII MANUFACTURING AND SUPPLY		48
8.1	Manufacture and Supply of Clinical Supply Requirements of Formulated Bulk Product	48
8.2	Finished Product Supply of Clinical Supply Requirements	48
8.3	Manufacture and Supply of Commercial Supply Requirements	48
8.4	Supply Agreement	49
8.5	Process Development and Manufacturing Plans	50
8.6	Manufacturing Shortfall	50
8.7	Manufacturing Compliance	50
ARTICLE IX PERIODIC REPORTS; PAYMENTS		51
9.1	Development Costs	51
9.2	Milestone Payments	51
9.3	Royalties	51
9.4	Sharing of Profits from Licensed Products	51
9.5	Periodic Reports	51
9.6	Funds Flow	52
9.7	Invoices and Documentation	53
9.8	Payment Method and Currency	53
9.9	Late Payments	53
9.10	Taxes	53
9.11	Adjustments to FTE Rates	53
9.12	Resolution of Payment Disputes	54
ARTICLE X DISPUTE RESOLUTION		54
10.1	Resolution of Disputes	54
10.2	Governance Disputes	54
10.3	Legal Disputes	54
10.4	Expert Panel	54
10.5	No Waiver	57
ARTICLE XI TRADEMARKS AND CORPORATE LOGOS		57
11.1	Corporate Names	57
11.2	Selection of Product Trademarks	57
11.3	Ownership of Product Trademarks	57
11.4	Prosecution and Maintenance of Product Trademark(s)	57
11.5	License to the Product Trademark(s)	57
11.6	Use of Corporate Names	58

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3326

Samsung Bioepis Exhibit 1017, pg. 3326

		Page
ARTICLE XII NEWLY CREATED INVENTIONS AND KNOW-HOW		58
12.1	Ownership of Newly Created Intellectual Property	58
12.2	Prosecution and Maintenance of Patent Rights	60
12.3	Interference, Opposition and Reissue	63
ARTICLE XIII INTELLECTUAL PROPERTY LITIGATION AND LICENSES		64
13.1	Third Party Infringement Suits	64
13.2	Patent Marking	65
13.3	Third Party Infringement Claims; New Licenses	65
ARTICLE XIV BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS		66
14.1	Books and Records	66
14.2	Audits and Adjustments	66
14.3	GAAP/IAS/IFRS	67
ARTICLE XV REPRESENTATIONS, WARRANTIES and Covenants		67
15.1	Due Organization, Valid Existence and Due Authorization; Financial Capability	67
15.2	Knowledge of Pending or Threatened Litigation	68
15.3	Additional Regeneron Representations, Warranties and Covenants	68
15.4	Disclaimer of Warranties	69
15.5	Mutual Covenants	69
ARTICLE XVI CONFIDENTIALITY		69
16.1	Confidential Information	69
16.2	Injunctive Relief	71
16.3	Publication of New Information	71
16.4	Disclosures Concerning this Agreement	71
ARTICLE XVII INDEMNITY		72
17.1	Indemnity and Insurance	72
17.2	Indemnity Procedure	74
ARTICLE XVIII FORCE MAJEURE		75
ARTICLE XIX TERM AND TERMINATION		75
19.1	Term/Expiration of Term	75
19.2	Termination Without Cause	76
19.3	Termination For Material Breach	78
19.4	Termination for Insolvency	78
19.5	Termination for Breach of Standstill or Lock-Up	79
19.6	Termination of Discovery Agreement	79
19.7	Effect of Termination	79
19.8	Survival of Obligations	80

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3327

Samsung Bioepis Exhibit 1017, pg. 3327

		Page
ARTICLE XX MISCELLANEOUS		81
20.1	Governing Law; Submission to Jurisdiction	81
20.2	Waiver	81
20.3	Notices	81
20.4	Entire Agreement	82
20.5	Amendments	82
20.6	Interpretation	82
20.7	Severability	82
20.8	Registration and Filing of the Agreement	82
20.9	Assignment	82
20.10	Successors and Assigns	83
20.11	Affiliates	83
20.12	Counterparts	83
20.13	Third-Party Beneficiaries	83
20.14	Relationship of the Parties	84
20.15	Limitation of Damages	84
20.16	Non-Solicitation	84
20.17	No Strict Construction	84

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3328

Samsung Bioepis Exhibit 1017, pg. 3328

LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), dated as of November 28, 2007 (the "Effective Date"), is by and between AVENTIS PHARMACEUTICALS INC., a corporation organized under the laws of the state of Delaware having a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807 ("Sanofi"), an indirect wholly owned subsidiary of sanofi-aventis, a company organized under the laws of France with its principal headquarters at 174, avenue de France, 75013 Paris, France ("Sanofi Parent"), SANOFI-AVENTIS AMERIQUE DU NORD, a partnership organized under the laws of France with its principal headquarters at 174 avenue de France, 75013 Paris, France ("Sanofi Amerique"), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of the state of New York having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Sanofi and Regeneron being sometimes referred to herein individually as a "Party" and collectively as the "Parties", and with Sanofi Amerique being a party to this Agreement for purposes of Sections 15.1, 15.2 and 20.11 only).

WHEREAS, concurrently with the execution and delivery of this Agreement, the Parties have entered into a Discovery and Preclinical Development Agreement (the "Discovery Agreement") whereby, upon the terms and conditions set forth therein, Regeneron will use its proprietary VelocImmune® technology and related suite of technologies with the objective of discovering Product Candidates (as defined below) which Sanofi may elect, in accordance with the Discovery Agreement, to advance into Development (as defined below) and thereupon automatically obtain from Regeneron a license of certain rights thereto upon the terms and conditions set forth herein;

WHEREAS, Sanofi and its Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory (each as defined below);

WHEREAS, Regeneron and Sanofi desire to collaborate on the Development, Manufacture and Commercialization of Licensed Products (each as defined below) in the Field in the Territory upon the terms and conditions set forth herein (the "Collaboration"); and

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I
DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Additional Major Market Country" shall mean any country in the Territory, other than the Major Market Countries referred to in clause (i) of the definition thereof, in which Net Sales in the immediately preceding Contract Year were ********** or more of

aggregate Net Sales in the Territory, and such designation shall remain effective from and after the determination of such Net Sales amount; provided, however, that a country shall not be deemed an Additional Major Market Country if, at the time that Net Sales in such country in a given Contract Year first exceed ********** of aggregate Net Sales in the Territory, the Parties mutually agree otherwise.

1.2 "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates. For purposes of this Agreement, neither Sanofi Pasteur nor Merial Limited, nor any of their respective subsidiaries or joint ventures, shall be deemed to be Affiliates of Sanofi or any of its Affiliates.

1.3 "Ancillary Agreements" means the Sanofi Stock Purchase Agreement and the Investor Agreement.

1.4 "Anticipated First Commercial Sale" shall mean, with respect to a Licensed Product in the Field, the date agreed upon by the JSC in advance as the expected date of First Commercial Sale of such Licensed Product in the Field in a country in the Territory.

1.5 "Approval" shall mean, with respect to each Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the Development, Manufacture or Commercialization of such Licensed Product in the Field in a regulatory jurisdiction anywhere in the world, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.

1.6 "Aventis LLC" shall mean sanofi-aventis US LLC (successor in interest under the Aventis Collaboration Agreement to Aventis Pharmaceuticals Inc.).

1.7 "Aventis Collaboration Agreement" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Aventis LLC and Regeneron, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3330

Samsung Bioepis Exhibit 1017, pg. 3330

Amendment, dated as of January 31, 2006, and Section 11.2 of the Sanofi Stock Purchase Agreement, as the same may be further amended from time to time.

1.8 "Aventis Stock Purchase Agreement" shall mean the Stock Purchase Agreement dated as of September 5, 2003 by and between Aventis Pharmaceuticals Inc. and Regeneron, as amended by Sections 4.2(b) and 4.4 of the Investor Agreement effective upon the execution and delivery of the Investor Agreement, and as may be further amended from time to time.

1.9 "BLA" shall mean, with respect to each Licensed Product, a biologics license application filed with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.

1.10 "Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, the United States or Paris, France are authorized or required by Law to remain closed.

1.11 "Clinical Supply Cost" shall mean (a) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture Formulated Bulk Product for Clinical Supply Requirements under the applicable Global Development Plan, (b) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture, comparator agent or placebo requirements for activities contemplated under the applicable Global Development Plan, (c) the Out-of-Pocket Cost and/or the Manufacturing Cost for filling, packaging, labeling and delivery of such Clinical Supply Requirements, comparator agent, combination agent and/or placebo, as the case may be, for activities contemplated under the applicable Global Development Plan and (d) any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of Clinical Supply Requirements. To the extent that manufacturing cost for comparator agent, combination agent or placebo includes any markup over Manufacturing Cost to the benefit of one of the Parties or its Affiliates, such markup shall be deducted in the calculation of Clinical Supply Cost.

1.12 "Clinical Supply Requirements" shall mean, with respect to a Licensed Product, the quantities of such Licensed Product which are required by a Party or the Parties for Development in the Field under this Agreement, including, without limitation, the conduct of research, pre-clinical studies and clinical trials in connection with a Development Plan and quantities of such Licensed Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the Territory.

1.13 "Co-Commercialize" or "Co-Commercialization" shall mean the act of Co-Promoting in a Co-Commercialization Country.

1.14 "Co-Commercialization Country" shall mean each country in which Regeneron has elected to Co-Promote a Licensed Product, so long as, after commencing such Co-Promotion, Regeneron is Co-Promoting at least one Licensed Product in such country.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3331

Samsung Bioepis Exhibit 1017, pg. 3331

1.15 "COGS" for a Licensed Product for a Quarter shall mean cost (calculated in accordance with IAS/IFRS) of Manufacturing the Licensed Product sold in the Field in the Territory in the Quarter.

1.16 "Commercial Overhead Charge" shall mean, on a country-by-country and Licensed Product-by-Licensed Product basis in the Territory, beginning in the Contract Year of First Commercial Sale in the applicable country, an amount (agreed upon by the JFC at least six (6) months prior to the Anticipated First Commercial Sale in the country) to cover **********, such amount to be determined by the JFC as of January 1 of each following Contract Year. For the avoidance of doubt, "Commercial Overhead Charge" shall not include any amounts included in Medical Post-Approval Cost, Sales Force Cost, Other Shared Expenses or Shared Commercial Expenses.

1.17 "Commercial Supply Cost" shall mean the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost for the Manufacture of Commercial Supply Requirements, including, without limitation, scale-up after First Commercial Sale, any filling, packaging and labeling costs, and any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.

1.18 "Commercial Supply Requirements" shall mean, with respect to each Licensed Product, quantities of Finished Product as are required to fulfill requirements for commercial sales, Non-Approval Trials and product sampling with respect to such Licensed Product in the Field in the Territory.

1.19 "Commercialize" or "Commercialization" shall mean, with respect to a Licensed Product, any and all activities directed to marketing, promoting (including, if applicable, Co-Promoting), detailing, distributing, importing, offering for sale, having sold and/or selling such Licensed Product in the Field in the Territory, including, without limitation, market research, obtaining Pricing Approvals, pre-launch marketing **********.

1.20 "Commercially Reasonable Efforts" shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a market-by-market and Licensed Product-by-Licensed Product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of the Licensed Product or alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitiveness factors. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the profit sharing nor other payments made or required to be made hereunder shall be factor weighed (that is, a Party may not apply lesser resources or efforts in support of a Licensed Product because it must share profits from sales of such Licensed Product or make any other payments hereunder).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3332

Samsung Bioepis Exhibit 1017, pg. 3332

1.21 "Committee" means any of the JSC, JDC, JCC, JMC, JFC, any CRCC, and any other committee established by the Parties or by the Committees referenced above, each as described in Article III (together with Working Groups or other committees contemplated herein or established in accordance with this Agreement).

1.22 "Competing Opt-Out Product" shall mean any Opt-Out Product having the same Target as a Licensed Product.

1.23 "Competing Product" shall mean, with respect to a Licensed Product, **********.

1.24 "Confidentiality Agreements" shall mean the confidentiality agreements between Regeneron and Sanofi Parent dated February 1, 2007 and October 23, 2007, respectively.

1.25 "Consolidated Payment Report" shall mean a consolidated Quarterly report prepared by Sanofi (based on information reported under Sections 5.4 and 9.5) setting forth in reasonable detail, for each Major Market Country in the Territory, for each Region in the Territory, and in the aggregate for all countries in the Territory, (a) Net Sales, COGS and Shared Commercial Expenses incurred by each Party for such Quarter, (b) Development Costs incurred by each Party for such Quarter, (c) Other Shared Expenses incurred by each Party for such Quarter, and (d) the Quarterly True-Up, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 2.

1.26 "Contract Sales Force" shall mean sales representatives employed by a Third Party.

1.27 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2008, and each succeeding consecutive twelve (12) month period thereafter during the Term. The last Contract Year of the Term shall begin on January 1 for the year during which termination or expiration of the Agreement will occur, and the last day of such Contract Year shall be the effective date of such termination or expiration.

1.28 "Controlling Party" shall mean **********.

1.29 "Co-Promote" or "Co-Promotion" shall mean the joint marketing and promotion of Licensed Product(s) by the Parties (or their respective Affiliates) under the same trademark in a Major Market Country pursuant to the applicable Country/Region Commercialization Plan.

1.30 "Country/Region Commercialization Budget" shall mean the budget for a particular calendar year approved by the JCC for the applicable Country/Region Commercialization Plan.

1.31 "Country/Region Commercialization Plan" shall mean, for each Reporting Country/Region, the three (3) year rolling plan for Commercializing Licensed Products in the Field in such country or Region and the related Country/Region Commercialization Budget and a

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3333

Samsung Bioepis Exhibit 1017, pg. 3333

non-binding budget forecast for the next two (2) calendar years, approved by the JCC, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Country/Region Commercialization Plan shall set forth, for each Licensed Product, the information, plans and forecasts set forth in Section 6.3.

1.32 "Country/Region Commercialization Committee", or "CRCC" , shall mean the committee established by the JCC for a particular Reporting Country/Region as described in Section 3.5.

1.33 "Detail" shall mean, with respect to each Licensed Product in the Field, a selling presentation for such product by a representative of each Party's sales force, or another employee of each Party who may be deemed to be part of the Commercialization effort for such Licensed Product (e.g., such as a key account manager, etc.).

1.34 "Develop" or "Development" shall mean, with respect to a Licensed Product, the following activities undertaken or performed after the Initial IND Filing Date for such Licensed Product: (a) activities relating to research, pre-clinical and clinical drug development of such Licensed Product in the Field, including, without limitation, test method development and stability testing, assay development, toxicology, pharmacology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, clinical studies (including research to design clinical studies), regulatory affairs, project management, drug safety surveillance activities related to clinical studies, the preparation and submission of Registration Filings but excluding activities necessary to obtain a Pricing Approval, reimbursement and/or listing on health care providers' and payers' formularies, (b) ********** and (c) any other research and development activities with respect to such Licensed Product in the Field, including, without limitation, activities to support the discovery of biomarkers and activities to support new product formulations, delivery technologies and/or new indications in the Field, either before or after the First Commercial Sale.

1.35 "Development Costs" shall mean costs incurred by a Party (for each Licensed Product, commencing with the first (1st) day of the month in which the Opt-In Notice (as such term is defined in the Discovery Agreement) for such Licensed Product is received by Regeneron) directly in connection with the Development of Licensed Products in the Field in accordance with this Agreement and the applicable Global Development Plan, including without limitation:

(a) all Out-of-Pocket Costs, including, without limitation, fees and expenses associated with obtaining Registration Filings and Marketing Approvals necessary for the Development and Commercialization of the Licensed Products in the Field under this Agreement;

(b) Development FTE Costs;

(c) Clinical Supply Costs;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3334

Samsung Bioepis Exhibit 1017, pg. 3334

(d) the costs and expenses incurred in connection with (i) Manufacturing process, formulation, cleaning, and shipping development and validation (other than validation batches which are sold), (ii), Manufacturing scale-up and improvements, (iii) stability testing, (iv) quality assurance/quality control development (including management of Third Party fillers, packagers and labelers), and (v) internal and Third Party costs and expenses incurred in connection with (A) qualification and validation of Third Party contract manufacturers and vendors and (B) subject to the terms of this Agreement, establishing a primary or secondary source supplier, including, without limitation, the transfer of process and Manufacturing technology and analytical methods, scale-up up to First Commercial Sale, process and equipment validation, cleaning validation and initial Manufacturing licenses, approvals and Regulatory Authority inspections (in each case, to the extent not included in Clinical Supply Costs or Commercial Supply Costs);

(e) any license fees and other payments under Licenses to the extent attributable to the Manufacture of Clinical Supply Requirements and/or the Development of Licensed Products in the Field under the Plans for the Territory subject to Section 13.3(e) in this Agreement; and

(f) any other costs or expenses specifically identified and included in the applicable Development Plan or included as Development Costs under this Agreement.

1.36 "Development FTE Cost" shall mean, for all Development activities performed in accordance with the Development Plan(s), including regulatory activities, the product of (a) the number of FTEs required for such Development activity as set forth in the approved Development Plan and (b) the Development FTE Rate. For the avoidance of doubt, the activity of contract personnel shall be charged as Out-of-Pocket Costs.

1.37 "Development FTE Rate" shall mean ******* in the first (1st) Contract Year, such amount to be adjusted as of January 1, 2009 and annually thereafter by the sum of (a) the average of the percentage increases or decreases, if any, in the US CPI and the ROW CPI for the twelve (12) months ending June 30 of the Contract Year prior to the Contract Year for which the adjustment is being made **********, the Parties shall meet to consider a revision to the Development FTE Rate.

1.38 "Development Plan" shall mean a Global Development Plan or an Initial Development Plan, as the context requires.

1.39 "Discovery Program" shall have the meaning set forth in the Discovery Agreement.

1.40 "EMEA" shall mean the European Medicines Evaluation Agency or any successor agency thereto.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3335

Samsung Bioepis Exhibit 1017, pg. 3335

1.41 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Sanofi Parent, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.

1.42 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.43 "Field" shall mean the treatment, prevention, palliation and/or diagnosis of any disease.

1.44 "Finished Product" shall mean a Licensed Product in the Field in its finished, labeled and packaged form, ready for sale to the market or use in clinical or pre-clinical trials, as the case may be.

1.45 "First Commercial Sale" shall mean, with respect to a Licensed Product in a country in the Territory, the first commercial sale of the Finished Product to non-Sublicensee Third Parties for use in the Field in such country (or group of countries) following receipt of Marketing Approval. Sales for test marketing or clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.

1.46 "Formulated Bulk Product" shall mean Licensed Product in the Field formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.

1.47 "FTE" shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes of Development shall be ***** per year.

1.48 "GAAP" shall mean generally accepted accounting principles as applicable in the United States.

1.49 "Global Commercialization Budget" shall mean the budget(s) for a particular Contract Year approved by the JCC for the applicable Global Commercialization Plan.

1.50 "Global Commercialization Plan" shall mean, with respect to a Licensed Product, the three (3) year rolling plan approved by the JSC for Commercializing such Licensed Product throughout the world, including the related Global Commercialization Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Global Commercialization Plan shall set forth (if not otherwise set forth in the applicable Country/Region Commercialization Plan(s)) for a Licensed Product, the information, plans and forecasts set forth in Section 6.2.

1.51 "Global Development Budget" shall mean the budget(s) for a particular Contract Year approved by the JSC for the applicable Global Development Plan.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3336

Samsung Bioepis Exhibit 1017, pg. 3336

1.52 "Global Development Plan" shall mean, with respect to a Licensed Product, the Initial Development Plan and the three (3) year rolling plan approved by the JSC for the worldwide Development of such Licensed Product, including the related Global Development Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this Agreement. For the avoidance of doubt, a Global Development Plan will not include Non-Approval Trials.

1.53 "Good Practices" shall mean compliance with the applicable standards contained in then-current "Good Laboratory Practices," "Good Manufacturing Practices" and/or "Good Clinical Practices," as promulgated by the FDA and all analogous guidelines promulgated by the EMEA or the ICH, as applicable.

1.54 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.55 "IAS/IFRS" shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.

1.56 "ICH" shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.57 "IND" shall mean, with respect to each Licensed Product in the Field, an Investigational New Drug Application filed with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside the United States.

1.58 "Indication" means any disease.

1.59 "Initial Development Plan" shall have the meaning set forth in the Discovery Agreement.

1.60 "Initial IND Filing Date" means, with respect to a Licensed Product, the date an IND for such Licensed Product is first filed.

1.61 "Investor Agreement" means the Investor Agreement by and among Sanofi Parent, Sanofi, Aventis LLC, Sanofi Amerique and Regeneron, substantially in the form of Exhibit B to the Sanofi Stock Purchase Agreement, which will be entered into concurrently with the closing under the Sanofi Stock Purchase Agreement.

1.62 "Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.

1.63 "Know-How" shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information, including marketing and supply information, (whether or not patentable or

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3337

Samsung Bioepis Exhibit 1017, pg. 3337

otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party's Patents or Patent Applications.

1.64 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

1.65 "Lead Regulatory Party" shall mean the Party having responsibility for preparing, prosecuting and maintaining Registration Filings and any Approvals for Licensed Products in the Field under this Agreement, and for related regulatory duties.

1.66 "Legal Dispute" shall mean any dispute related to a Party's alleged failure to comply with this Agreement or the validity, breach, termination or interpretation of this Agreement.

1.67 "License" shall mean any license from a Third Party approved by the JSC required for the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.

1.68 "Licensed Products" shall mean (i) Product Candidates as to which Sanofi has exercised its Opt-In Rights in accordance with Section 5.4 of the Discovery Agreement, (ii) any Competing Product that is included in the Collaboration pursuant to Section 2.6(c) below, (iii) REGN88 (IL-6RmAB) and Delta-like ligand-4(D-ll4) and (iv) ********** (as defined in the Discovery Agreement) once included in the Collaboration pursuant to Section 2.11(b) of the Discovery Agreement.

1.69 "Major Market Country" shall mean any of the following: **********.

1.70 "Manufacture" or "Manufacturing" shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and/or storage of Formulated Bulk Product, Finished Product, placebo or a comparator agent, as the case may be.

1.71 "Marketing Approval" shall mean an approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in an indication in the Field in any country, but excluding any separate Pricing Approval.

1.72 "Manufacturing Plan" shall mean the manufacturing plan as prepared by the JMC as described in Section 8.5.

1.73 "Medical Post-Approval Cost" shall mean, for Licensed Product(s) in each country in the Territory, the product of (a) the number of office-based people supporting (i) the coordination of Non-Approval Trials, (ii) post-Approval non-clinical pharmacovigilance, (iii) the maintenance of Approvals, and (iv) Pricing Approvals (with the number and the method of calculating such number set forth in the applicable Country/Region Commercialization Plan or Global Commercialization Plan) and (b) the applicable Medical Post-Approval FTE Rate. The calculation of the number of people in (a) above will be designed to ensure the proper reporting

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3338

Samsung Bioepis Exhibit 1017, pg. 3338

and auditing of such information in accordance with this Agreement. For the avoidance of doubt, the activities of contract personnel shall be charged as an Out-of-Pocket Cost.

1.74 "Medical Post-Approval FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis in the Territory (determined based on the location of the medical affairs professional), a rate agreed upon in local currency by the Parties prior to the expected start of the first Non-Approval Trial in such Region or Major Market Country, as applicable, based upon the fully burdened cost of medical affairs professionals of pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Medical Post-Approval FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.75 "Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of Licensed Products in the Field in the Territory by or on behalf of a Party or its Affiliates or Sublicensees to Third Parties, less the following deductions, determined in accordance with IAS/IFRS (or GAAP for the US) consistently applied:

(a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Licensed Products;

(b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;

(c) chargebacks and other amounts paid on sale or dispensing of Licensed Products;

(d) Third Party cash rebates and chargebacks related to sales of Licensed Products, to the extent allowed;

(e) retroactive price reductions that are actually allowed or granted;

(f) compulsory refunds, credits and rebates directly related to the sale of Licensed Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or government regulations;

(g) freight, postage, shipment and costs (or wholesale fees in lieu of those costs) and customs duties incurred in delivering Licensed Products that are separately identified on the invoice or other documentation;

(h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of Licensed Products, which are separately identified on the invoice or other documentation; and

(i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Product falling within

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3339

Samsung Bioepis Exhibit 1017, pg. 3339

categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof.

Net Sales in currency other than United States Dollars shall be translated into United States Dollars according to the provisions of Section 9.8 of this Agreement. Sales between the Parties, or between the Parties and their Affiliates or Sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if Sanofi or its Affiliate or Sublicensee sells such Licensed Products in the form of a combination product containing any Licensed Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), then prior to the First Commercial Sale of such Combination Product, the Parties shall agree through the JFC to the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, Immunoconjugates (as such term is defined in the Discovery Agreement) shall not be deemed Combination Products.

Solely for the purposes of Section 2.6(d) of this Agreement, the term "Licensed Product" as used in the definition of Net Sales shall refer to Opt-Out Products.

1.76 "New Information" shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public, which may arise or be conceived or developed by either Party or its Affiliates, or by the Parties or their Affiliates jointly, during the Term pursuant to this Agreement, to the extent specifically related to any Licensed Product in the Field, including, without limitation, information and data included in any Plans or Registration Filings made under this Agreement.

1.77 "Non-Approval Trials" shall mean any post-marketing surveys, registries and clinical trials post-first Marketing Approval not intended to gain additional labeled Indications, but excluding any post-first Marketing Approval clinical trials required by Regulatory Authorities to maintain Marketing Approvals of existing labeled Indication(s).

1.78 "Opt-In Right" shall have the meaning set forth in the Discovery Agreement.

1.79 "Opt-Out Product" shall mean a Licensed Product as to which this Agreement has been terminated in accordance with Section 19.2. For clarity, an Early Development Opt-Out Product shall not constitute an Opt-Out Product.

1.80 "Other Shared Expenses" shall mean those costs and expenses specifically referred to in Sections 7.6, 12.1(a), 12.2(e), 12.3(b), 13.1(c), 13.3(b), 13.3(d) and 17.1(c).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3340

Samsung Bioepis Exhibit 1017, pg. 3340

1.81 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates in accordance with a Plan, if applicable.

1.82 "Party Information" shall mean any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, ideas, discoveries and materials (whether or not patentable or protectable as a trade secret) not generally known to the public regarding a Party's or its Affiliates' technology, products, business or objectives, in each case, other than New Information, which are disclosed or made available by a Party or such Party's Affiliates to the other Party or the other Party's Affiliates in connection with this Agreement.

1.83 "Patent Application" shall mean any application for a Patent.

1.84 "Patent Rights" shall mean unexpired Patents and Patent Applications.

1.85 "Patents" shall mean patents and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof and supplemental protection certificates relating thereto, and all counterparts thereof in any country in the world.

1.86 "Person" shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.

1.87 "Phase 3 Trial" shall mean a clinical trial that is designed to gather further evidence of safety and efficacy of a Licensed Product in the Field (and to help evaluate its overall risks and benefits) and is intended to support Marketing Approval for a Licensed Product in the Field in one or more countries in the Territory. A Phase 3 Trial typically follows at least one dose ranging clinical trial to evaluate further the efficacy and safety of a Licensed Product in the Field in the targeted patient population and to help define the optimal dose and/or dosing regimen.

1.88 "Plan" shall mean any Country/Region Commercialization Plan, Global Commercialization Plan, Global Development Plan, Initial Development Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.

1.89 "Positive Phase 3 Trial Results" shall mean a Phase 3 Trial that meets its primary end-point as defined in the study protocol for such Phase 3 Trial, and the safety profile supports continued clinical testing in the applicable Indication and/or filing of an application for Marketing Approval.

1.90 "Pre-Launch Marketing Expenses" shall mean, with respect to a Licensed Product, on a country-by-country basis in the Territory, with respect to each Licensed Product, all Commercialization expenses to support such Licensed Product in the Field incurred **********.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3341

Samsung Bioepis Exhibit 1017, pg. 3341

1.91 "Pricing Approval" shall mean such approval, agreement, determination or governmental decision establishing prices for a Licensed Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.92 "Product Candidate" shall have the meaning set forth in the Discovery Agreement.

1.93 "Product Trademark" shall mean, with respect to each Licensed Product in the Field in the Territory, the trademark(s) selected by the JCC and approved by the JSC for use on such Licensed Product throughout the Territory and/or accompanying logos, slogans, trade names, trade dress and/or other indicia of origin, in each case as selected by the JCC and approved by the JSC.

1.94 "Promotional Materials" shall mean, with respect to each Licensed Product, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, promotion and sale of such Licensed Product in the Field in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.

1.95 "Quarter" or "Quarterly" shall refer to a calendar quarter, except that the first (1st) Quarter shall commence on the Effective Date and extend to the end of the then-current calendar quarter and the last calendar quarter shall extend from the first day of such calendar quarter until the effective date of the termination or expiration of the Agreement.

1.96 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and any Know-How of Regeneron or any of its Affiliates.

1.97 "Regeneron Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program or the Collaboration owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Know-How and Know-How included in Joint Inventions) with the right to sublicense the same that relate to a Licensed Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Licensed Product in the Field, including, without limitation, New Information.

1.98 "Regeneron Patent Rights" shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Patent Rights and Patent Rights included in Joint Inventions), with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Licensed Product in the Field, but only to such extent.

1.99 "Region" shall mean such countries or group of countries as determined by the JCC.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3342

Samsung Bioepis Exhibit 1017, pg. 3342

1.100 "Registration Filing" shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any IND or Marketing Approval application in the Field.

1.101 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement. The term "Regulatory Authority" includes, without limitation, the FDA, the EMEA and the Japanese Ministry of Health, Labour and Welfare.

1.102 "Reporting Country/Region" shall mean each Major Market Country, and each other country or Region for which a Country/Region Commercialization Committee has been established by the JCC.

1.103 "Rest of World" or "ROW" shall mean all Rest of World Countries.

1.104 "Rest of World Country" shall mean any country in the Territory other than the United States.

1.105 "ROW CPI" shall mean the "EU15 CPI" (or its successor equivalent index), which is published monthly and available via *The Bloomberg Professional*, as published by Bloomberg L.P.

1.106 "Sales Force Cost" shall mean, for Licensed Product(s) in each country in the Territory, the product of (a) the number of detailing people (with the number and the method of calculating such number set forth in the applicable Country/Region Commercialization Plan or Global Commercialization Plan), and (b) **********. The calculation of the number of detailing people in (a) above will be based on **********. For the avoidance of doubt, the activities of contract personnel, including contract Sales Force, shall be charged as Out-of-Pocket Costs.

1.107 "Sales Force FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis (determined based on the location of the sales representative), a rate agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale in the Region or Major Market Country, as applicable, based upon the fully burdened cost of sales representatives of pharmaceutical companies in the Field in the applicable country, and including an allocation of regional and country sales force management cost, to be approved six (6) months prior to the first Commercial Sale, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Sales Force FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs, information systems and allocated costs, such as, for example, allocated overhead costs.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3343

Samsung Bioepis Exhibit 1017, pg. 3343

1.108 "Sanofi Intellectual Property" shall mean the Sanofi Patent Rights and the Sanofi Know-How.

1.109 "Sanofi Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program or the Collaboration owned by, licensed to or otherwise held by Sanofi or its Affiliates (other than Regeneron Know-How and Know-How included in Joint Inventions) with the right to sublicense the same that relate to a Licensed Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Licensed Product in the Field, including, without limitation, New Information.

1.110 "Sanofi Patent Rights" shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Patent Rights and Patent Rights included in Joint Inventions), with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Licensed Product in the Field, but only to such extent.

1.111 "Sanofi Stock Purchase Agreement" means the Stock Purchase Agreement dated as of the Effective Date by and between Sanofi Amerique, Aventis LLC and Regeneron.

1.112 "Shared Commercial Expenses" shall mean the sum of the following items, in each case to the extent directly attributable to Commercialization of Licensed Products in the Field in the Territory in accordance with an approved Country/Region Commercialization Plan or Global Commercialization Plan:

(a) ********** to cover the cost of distribution, freight, insurance and warehousing, related to the sale of Licensed Products in the Field in the Territory, less any amount deducted from Net Sales pursuant to clause (g) of the definition of Net Sales;

(b) bad debt attributable to Licensed Products in the Field sold in the Territory;

(c) Sales Force Cost;

(d) Medical Post-Approval Cost;

(e) Out-of-Pocket Costs related to (i) the marketing, advertising and/or promotion of Licensed Products in the Field in the Territory (including, without limitation, pricing activities, commercial pharmacovigilance, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for Licensed Products in the Field in the Territory and (iii) the preparation of training and communication materials for Licensed Products in the Field in the Territory;

(f) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of Licensed Products in the Field in the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3344

Samsung Bioepis Exhibit 1017, pg. 3344

Territory (including, without limitation, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion relate to both Licensed Products and other products developed or commercialized by Sanofi or its Affiliates as agreed upon in an approved Global Commercialization Plan or Country/Region Commercialization Plan;

(g) Out-of-Pocket Costs related to Non-Approval Trials for Licensed Products in the Field in the Territory, including, without limitation, the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies, in each case, to the extent not included in Commercial Supply Cost;

(h) Out-of-Pocket Costs related to Pricing Approvals and the maintenance of all Approvals directly related to the Commercialization of Licensed Products in the Field in the Territory;

(i) Commercial Overhead Charge;

(j) Pre-Launch Marketing Expenses;

(k) Out-of-Pocket Costs related to regulatory affairs activities, other than activities to secure Registration Filing of indications and line extensions; and

(l) any other costs or expenses directly related to the Commercialization of a Licensed Product after First Commercial Sale of such Licensed Product and not included in clauses (a) through (k) above.

The foregoing shall not include any costs which have been included in Development Costs. For clarity, it is the intent of the Parties that costs and headcount included in the foregoing will be fairly allocated to the Licensed Products in the Field in the Territory (to the extent that any Shared Commercial Expense is attributable, in part, to products or activities other than the Licensed Products in the Field in the Territory) and, in each case, will only be included once in the calculation of the Quarterly True-Up.

1.113 "Shared Phase 3 Trial Costs" shall mean Development Costs associated with Phase 3 Trials of any Licensed Product incurred after the receipt of first Positive Phase 3 Trial Results for such Licensed Product.

1.114 "Sublicensee" shall mean a Third Party or an Affiliate to whom Sanofi will have granted a license or sublicense under Sanofi's rights pursuant to Section 4.3 to Commercialize Licensed Products in the Field in the Territory. For the avoidance of doubt, a "Sublicensee" will include a Third Party to whom Sanofi will have granted the right to distribute Licensed Products in the Field wherein such distributor pays to Sanofi a royalty (or other amount) based upon the revenues received by the distributor for the sale (or resale) of Licensed Products by such distributor.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3345

Samsung Bioepis Exhibit 1017, pg. 3345

1.115 "Target" shall mean any gene, receptor, ligand or other molecule (a) associated with a disease activity that may be modified by direct interaction with a Licensed Product or (b) to which a Licensed Product binds.

1.116 "Terminated Licensed Product"shall mean a Licensed Product as to which this Agreement has been terminated in accordance with its terms in accordance with Article XIX, and shall include any Opt-Out Product.

1.117 "Termination Notice Period" shall mean the Sanofi Termination Notice Period or the Regeneron Termination Notice Period, as applicable.

1.118 "Territory" shall mean all the countries and territories of the world.

1.119 "Third Party" shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.

1.120 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.

1.121 "US CPI" shall mean the Consumer Price Index — All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

1.122 "Valid Claim" shall mean (a) a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; or (b) a claim of a Patent Application, which claim has been pending less than five (5) years from the original priority date of such claim in a given jurisdiction, unless or until such claim thereafter issues as a claim of an issued Patent (from and after which time the same shall be deemed a Valid Claim subject to paragraph (a) above).

1.123 Additional Definitions. Each of the following definitions is set forth in the Sections (or Schedules) of this Agreement indicated below:

DEFINITION	SECTION/SCHEDULE
Acquired Entity	2.6(c)
Acquiring Party	2.6(c)
Agreement	Preamble
Alliance Manager	3.2(a)
Annual True-Up	SCHEDULE 2
Applicable ROW Percentages	SCHEDULE 2
Budget Dispute	Section 3.11(b)
Collaboration	Preamble
Collaboration Purpose	3.1(b)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3346

Samsung Bioepis Exhibit 1017, pg. 3346

DEFINITION	SECTION/SCHEDULE
Combination Product	1.76
Cost	SCHEDULE 1
Damages	17.1(a)
Default Interest Rate	9.9
Development Balance	SCHEDULE 2
Discovery Agreement	Preamble
Disputed Budget	Section 3.11(b)
Early Development Opt-Out Product	5.6
Effective Date	Preamble
Excluded Rights	4.3
Expert Panel	10.4(a)
First Year	5.3
Force Majeure	ARTICLE XVIII
Global Development Budget(s)	5.3
Governance Dispute	10.2
Incomplete Activity	5.3
Indemnified Party	17.2
Indemnifying Party	17.2
JCC	3.1(a)
JDC	3.1(a)
JFC	3.1(a)
JMC	3.1(a)
Joint Invention	12.1(b)
JSC	3.1(a)
Lead Litigation Party	13.1(c)
Manufacturing Cost	SCHEDULE 1
Manufacturing Notice	8.3(a)
Manufacturing Plan	8.5
Marketing Guidelines	3.4(b)(vi)
Maximum Regeneron Effort	6.5(e)(i)
Modified Clause	20.7
Non-Acquiring Party	2.6(c)
Non-Approval Trials	6.2(h)
Non-Incurred Amount	5.3
Opt-Out Partner	2.6(d)
Opt-Out Product Notice	2.6(c)
OverPaying Party	Section 13.3(e)
Party(ies)	Preamble
Patent Jurisdictions	12.2(a)
POC Principal Party	5.2
POC Time	5.2
Post-POC Principal Party	5.2
Publishing Party	16.3
Quarterly True-Up	SCHEDULE 2
Regeneron	Preamble

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3347

Samsung Bioepis Exhibit 1017, pg. 3347

DEFINITION	SECTION/SCHEDULE
Regeneron Commitment Level	6.5(e)(i)
Regeneron Early Development Opt-Out Right	5.6
Regeneron Early Opt-Out Notice	5.6
Regeneron Indemnitees	17.1(a)
Regeneron Profit Split	SCHEDULE 2
Regeneron Reimbursement Amount	SCHEDULE 2
Regeneron Sole Inventions	12.1(a)
Regeneron Termination Notice Period	19.2(b)
Reimbursement Payment	SCHEDULE 2
Required Divestiture Notice Period	2.6(c)
Rest of World Profit Split	SCHEDULE 2
Royalty Term	9.3
ROW Profit Split	SCHEDULE 2
ROW Profit Split Annual True-Up	SCHEDULE 2
Sanofi	Preamble
Sanofi Amerique	Preamble
Sanofi Indemnitees	17.1(b)
Sanofi Parent	Preamble
Sanofi Sole Inventions	12.1(a)
Sanofi Termination Notice Period	19.2(a)
SDEA	7.4
Shared Phase 3 Trial Costs Balance	SCHEDULE 2
Sole Developer	2.6(d)
Sole Inventions	12.1(a)
Succeeding Year(s)	5.3
Target Labeling	7.2(d)
Target ROW Profit Split	SCHEDULE 2
Technical Development Matter	10.2
Term	19.1(a)
Third Party	2.6(c)
Third Party Acquisition	2.6(c)
U.S. Profit Split	SCHEDULE 2
US Profits	SCHEDULE 2
VelocImmune Royalties	Section 13.3(e)
Working Group	3.1(a)

ARTICLE II
COLLABORATION

2.1 Scope of Collaboration. Upon and subject to terms and conditions of this Agreement, the Parties will cooperate in good faith to Develop, Manufacture and Commercialize Licensed Products in the Field in the Territory in such a manner so as to optimize the commercial potential of each Licensed Product. The Parties shall establish various Committees as set forth in Article III of this Agreement to oversee and/or coordinate the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory, and each

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3348

Samsung Bioepis Exhibit 1017, pg. 3348

Party shall, subject to the terms and conditions set forth in Article XVI, provide (or cause its Affiliates to provide) to any relevant Committee any necessary Party Information, New Information and such other information and materials as may be reasonably required for the Parties to operate effectively and efficiently under and in accordance with the terms and conditions of this Agreement.

2.2 Compliance With Law. Both Sanofi and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.

2.3 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement and the consummation by such Party of the transactions contemplated by this Agreement and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required to be made by such Party under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings. Each Party will furnish to the other Party all information in its possession or under its control required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.4 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Licenses to which it is a party and to notify the other Party of any terms or conditions in any such License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement, including any sublicense under a License referenced in subsection (a) above, to which it is a party and that is related to the Collaboration, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder. Neither Party may terminate or amend any License or any other material agreement entered into pursuant to a Plan without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, if the amendment or termination imposes any material liability or restriction on either Party with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory.

2.5 Plans. The Parties shall undertake all Development and Commercialization activities under this Agreement solely in accordance with the Committee approved Plans. The Parties may agree to amend all Plans and budgets from time to time as circumstances may require.

2.6 Limitation on Exercise of Rights Outside of Collaboration.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3349

Samsung Bioepis Exhibit 1017, pg. 3349

(a) Non-Compete. Without limitation of and in addition and subject to Section 2.8 of the Discovery Agreement, during the Term, except as set forth in this Agreement or Section 2.8 of the Discovery Agreement, neither Party nor any of its Affiliates, either alone or through any Third Party, shall Develop or Commercialize any Competing Product.

(b) Regeneron Sole Development. If Regeneron presents a proposal to the JDC to undertake additional clinical trials not contemplated in a Global Development Plan to support a Licensed Product in the Field and the JDC fails to approve the proposal within the timeframe established by the JDC pursuant to Section 5.5, then Regeneron may, at its option and at its sole expense, conduct such additional clinical trial(s) outside the scope of the applicable Global Development Plan; provided, however, Regeneron must first present the proposed protocols and clinical trial designs to Sanofi for approval, such approval not to be unreasonably withheld or delayed and, for other than Non-Approval Trials, shall also present to Sanofi the related budgets for Clinical Supply Costs and Out-of-Pocket Costs and applicable FTE costs (provided that such budgets shall be provided for informational purposes only and may not be used to disapprove such protocols and designs). Regeneron shall also provide to Sanofi drug safety data from such additional clinical trials in accordance with Section 7.4. The Sanofi representatives on the JDC may disapprove any such protocols or clinical trial designs for reasons of safety or Sanofi reasonably believes that the development as described in this Section 2.6(b) would have a material adverse effect on the overall development strategy for the Licensed Product and/or the commercial viability of such License Product, including the magnitude of sales for such Licensed Product. If, in compliance with this Section 2.6(b), Sanofi does not approve any such protocols or clinical trial designs for reasons as described herein, Regeneron may not proceed with the proposed clinical trials unless Regeneron disputes such disapproval and until the dispute has been resolved, as provided in Section 3.11(b) and, if necessary, Section 10.4, in Regeneron's favor. In the event that Regeneron conducts any such additional clinical trials, all results, Know-How and Patent Rights generated in or arising from any such clinical trial shall be subject to the grants of rights pursuant to Article IV of this Agreement. For the avoidance of doubt, no consideration or reimbursement shall be paid to Regeneron with respect to the conduct of any such additional clinical trials; provided, however, that if the Parties subsequently agree to commence a further clinical trial based on the results of such additional clinical trial(s) or data is used from such additional clinical trial(s) to support an Approval in the Territory, then Sanofi shall be required to reimburse Regeneron for ********** of the actual Out-of-Pocket Costs and Clinical Supply Costs and applicable FTE costs incurred in connection with the conduct of such additional clinical trial(s) that are consistent with the budgets provided to Sanofi pursuant to this Section 2.6(b) and the other terms of this Agreement. Publication of any results or data obtained in conducting the additional clinical trial(s) allowed under this Section 2.6(b) shall be subject to Article XVI.

(c) Company Acquisitions. Notwithstanding Section 2.6(a), if as the result of an acquisition of a Third Party (such acquisition a "Third Party Acquisition) by a Party or one or more of its Affiliates (the "Acquiring Party"), the Acquiring Party

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3350

Samsung Bioepis Exhibit 1017, pg. 3350

acquires rights to a product that is a Competing Product (the "Acquired Competing Product") to a Licensed Product (the "Competing Licensed Product"), the Acquiring Party, at its sole discretion, shall do one of the following: (W) present a proposal to the JDC to include the Acquired Competing Product in the Collaboration in accordance with Section 2.6(c)(i); (X) deliver to the other Party (the "Non-Acquiring Party") a termination notice, pursuant to Section 19.2(a) or 19.2 (b), as appropriate, and Section 2.6(c)(ii), with regard to the Competing Licensed Product; or (Y) transfer its rights in the Acquired Competing Product to a Third Party pursuant to Section 2.6(c)(iii).

(i) Proposal for Inclusion. If the Acquiring Party chooses this alternative, within ten (10) Business Days after the closing of such Third Party Acquisition, the Acquiring Party shall present a proposal to the JDC to include such Acquired Competing Product in the Collaboration based on the terms of this Agreement. As part of such presentation, the Acquiring party shall provide the JDC with all information with respect to such Acquired Competing Product reasonably available to the Acquiring Party and material to a decision by the Non-Acquiring Party's representatives on the JDC as to whether to approve the inclusion of such Acquired Competing Product in the Collaboration. The JDC shall, on or before the date which is twenty (20) Business Days after the closing of such Third Party Acquisition, decide whether to approve the inclusion of such Acquired Competing Product in the Collaboration under the terms of this Agreement. If the JDC timely approves the inclusion of such Acquired Competing Product in the Collaboration, then upon the closing of such Third Party Acquisition the Acquired Competing Product shall automatically be included in the Collaboration as a Licensed Product hereunder. If the JDC does not approve such inclusion, the Acquiring Party shall elect whether to deliver to the Non-Acquiring Party a termination notice, pursuant to Section 19.2(a) or 19.2 (b), as appropriate, and Section 2.6(c)(ii), with regard to the Competing Licensed Product or transfer its rights to the Acquired Competing Product to a Third Party (without any consideration or payment to the Non-Acquiring Party in accordance with Section 2.6(c)(iii) below).

(ii) Termination of Licensed Product. If the Acquiring Party chooses this alternative, the Acquiring Party shall deliver to the Non-Acquiring Party, within ten (10) Business Days after the decision of the JDC not to include the Acquired Competing Product in the Collaboration pursuant to Section 2.6(c)(i), a termination notice pursuant to Section 19.2(a) or 19.2(b), as applicable, with respect to the Competing Licensed Product (the "Opt-Out Product Notice"). The provisions of Section 19.2(a) or 19.2(b), as applicable, and the provisions of Sections 19.7, 19.8 and Schedule 4 or 5, as applicable, shall then apply to such Competing Licensed Product. For the avoidance of doubt, such Competing Licensed Product shall then be an Opt-Out Product, and notwithstanding any other provision of this Agreement, the Acquiring Party shall be deemed (without any requirement of notice to the Non-Acquiring Party) to have irrevocably ceded all decision-making authority with respect to such Opt-Out Product to the Non-Acquiring Party. In addition, if such Opt-Out Product is being marketed and sold

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3351

Samsung Bioepis Exhibit 1017, pg. 3351

at the time of the closing of the Third Party Acquisition, then during the Sanofi Termination Notice Period or Regeneron Termination Notice Period, as applicable, the following shall apply:

(1) In any Quarter in which the U.S. Profits are positive, the U.S. Profit Split shall be zero percent (0%) to the Acquiring Party and one hundred percent (100%) to the Non-Acquiring Party, and in any Quarter in which the ROW Profits are positive, the ROW Profit Split shall be zero percent (0%) to the Acquiring Party and one hundred percent (100%) to the Non-Acquiring Party.

(2) In any Quarter, in which U.S. Profits are negative, the U.S. Profit Split shall be one hundred percent (100%) to the Acquiring Party and zero percent (0%) to the Non-Acquiring Party, and in any Quarter in which ROW Profits are negative, the ROW Profit Split shall be one hundred percent (100%) to the Acquiring Party and zero percent (0%) to the Non-Acquiring Party.

(iii) Transfer of Rights. If the Acquiring Party chooses this alternative, the Acquiring Party shall commit in writing to the Non-Acquiring Party, within ten (10) Business Days after the closing of such Third Party Acquisition, to license or otherwise transfer rights to such Acquired Competing Product to a Third Party (without any consideration or payment to the Non-Acquiring Party) and/or cease all development, manufacturing and/or commercialization, as applicable, of such Acquired Competing Product within six (6) months after the closing of the Third Party Acquisition, and shall do so within such six (6) month period.

(iv) Required Divestiture of Licensed Product. Notwithstanding any of the foregoing in this Section 2.6(c), in the event the Acquiring Party believes, based on the written advice of its counsel, that it is required by Law to divest its interest either in the Acquired Competing Product or the Competing Licensed Product, the Acquiring Party may terminate this Agreement with respect to such Competing Licensed Product pursuant to Section 19.2(a) or 19.2 (b), as appropriate, Section 2.6(c)(ii) and this Section 2.6(c)(iv), with regards to the Competing Licensed Product, or transfer its interest in the Competing Licensed Product pursuant to Section 2.6(c)(iii). If the Acquiring Party terminates this Agreement with respect to the Competing Licensed Product pursuant to this Section 2.6(c)(iv), it shall give the Non-Acquiring Party the maximum advance notice (up to twelve (12) months) of termination consistent with such divestiture requirement imposed by Law (the "Required Divestiture Notice Period"), following which the provisions of 2.6(c)(ii) shall apply and the Competing Licensed Product shall be an Opt-Out Product. During this period, the Acquiring Party will reasonably cooperate (at the Acquiring Party's sole cost and expense) with the Non-Acquiring Party to enable the Non-Acquiring Party to assume, within the Required Divestiture Notice Period, the continued Development,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3352

Samsung Bioepis Exhibit 1017, pg. 3352

Manufacture and Commercialization of such Opt-Out Product in the Field in the Territory. The Acquiring Party shall also be responsible for, and shall promptly pay upon demand, all reasonable costs and expenses incurred by the Non-Acquiring Party in assuming such continued Development, Manufacture and Commercialization of such Opt-Out Product to the extent such costs and expenses, other than capital investments, would not have been incurred and/or would have been paid by the Acquiring Party, absent such Acquiring Party's termination with respect to such Opt-Out Product pursuant to Section 19.2(a) or (b). For the avoidance of doubt, if the Required Divestiture Notice Period is less than the twelve (12) months required by Section 19.2, the Acquiring Party shall have continuing payment obligations (though no performance obligations beyond those described above) to the Non-Acquiring Party with respect to such Opt-Out Product for the entire Sanofi Termination Notice Period (if Sanofi is the Acquiring Party) or Regeneron Termination Notice Period (if Regeneron is the Acquiring Party).

(d) Subject to the further provisions of this Section 2.6(d), in the case of any Opt-Out Product, the non-terminating Party (the "Sole Developer") shall have the right to Develop and Commercialize such Opt-Out Product, unless such Opt-Out Product is (or becomes) a Competing Opt-Out Product, in which case the Sole Developer may not (either directly or through an Affiliate or Third Party), Develop or Commercialize such Competing Opt-Out Product for a period of ******** following the date it becomes a Competing Opt-Out Product (or, if shorter, such period ending on the date such Competing Opt-Out Product ceases to be a Competing Opt-Out Product), unless otherwise agreed by the terminating Party (the "Opt-Out Partner"). If an Opt-Out Product is Commercialized by the Sole Developer (either directly or through an Affiliate or Third Party) in compliance with this Section 2.6(d), then the Sole Developer shall pay the Opt-Out Partner royalties based on Net Sales of such Opt-Out Product and the stage of Development of the Licensed Product at the time it became an Opt-Out Product, at the royalty rate(s) described on Exhibit A. Notwithstanding the foregoing or any other provision of this Agreement, in the case of any Opt-Out Product, including any Competing Opt-Out Product, resulting from termination of this Agreement with respect to a Licensed Product pursuant to Section 19.2 in the circumstances described in Section 2.6(c), the Sole Developer shall have no obligation either to delay Developing or Commercializing, or to pay royalties with respect to, such Opt-Out Product.

(e) Clinical Trials for Combination Products. Notwithstanding anything in this Section 2.6(e) to the contrary, each Party and/or its respective Affiliates shall be entitled to (i) initiate, sponsor and/or conduct a clinical trial and/or (ii) participate, directly or indirectly, whether through the provision of funds, grants or otherwise, in any clinical trial, initiated, sponsored and/or conducted by any Third Party, in each of the foregoing cases with respect to the combination of any Party's (or its Affiliate's) product, together with any Competing Product that has been granted a Marketing Approval for at least one Indication in the applicable country, unless (A) a Licensed Product Developed under this Agreement has been granted a Marketing Approval in the applicable country for use in combination with such Party's (or its Affiliate's) product in the same

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3353

Samsung Bioepis Exhibit 1017, pg. 3353

Indication(s) as the one to be studied in the intended clinical trial with the Competing Product which is not approved in such Indication or (B) both the Competing Product and a Licensed Product Developed under this Agreement have been granted a Marketing Approval in the applicable country for use in combination with such Party (or its Affiliate's) product as the same Indication to be studied in the intended clinical trial with the Competing Product and the relevant labeling of both the Licensed Product and the Competing Product for such Indication is substantially similar. For any combination study with a Competing Product covered by this Section 2.6(e), the applicable Party shall notify the other Party prior to initiating such trial, such notice to include a brief synopsis of the protocol and a description of the Party's (or its Affiliate's) role(s) and responsibilities in connection with the study. Further, for any combination study with a Competing Product covered by this Section 2.6(e), each Party shall promptly provide the other Party with available results of such combination study, unless such disclosure is prohibited by Law or contract. Each Party and/or its Affiliates shall be entitled to use data from clinical trials permitted by this Section 2.6(e) to promote the combination of such Party product together with such Competing Product, unless a Licensed Product Developed has been granted a Marketing Approval in the applicable country for use in combination with such Third Party product, in the same Indication. Neither Party nor its respective Affiliates shall receive any compensation or other payments (either in cash or in kind) based on the development, promotion, or sale of a Competing Product. Neither Party will intentionally delay the commencement, enrollment or completion of a clinical study of a Licensed Product as a result of any ongoing or pending clinical trial permitted by this Section 2.6(e). For the avoidance of doubt, neither Party nor its respective Affiliates shall use or disclose any Party Information or New Information subject to the confidentiality provisions of Article XVI in connection with any of the activities described in this Section 2.6(e).

ARTICLE III
MANAGEMENT

3.1 Committees/Management.

(a) The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee (the "JSC"), a Joint Development Committee (the "JDC"), a Joint Commercialization Committee (the "JCC"), CRCCs to the extent provided in Section 3.5, and such other commercialization sub-committee as JCC shall deem to be appropriate, a Joint Manufacturing Committee ("JMC"), a Joint Finance Committee (the "JFC") and such other Committees as the Parties deem appropriate. The JSC, JDC, JFC and JMC shall each be established within thirty (30) days after the Effective Date. The JCC shall be established at least two (2) years prior to the anticipated filing date for Marketing Approval for the first Licensed Product under this Agreement. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future and not described herein) and may be further designated by the JSC. From time to time, each Committee may establish working groups (each, a "Working Group") to oversee particular projects or

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3354

Samsung Bioepis Exhibit 1017, pg. 3354

activities, and each such Working Group shall be constituted and shall operate as the Committee which establishes the Working Group determines.

(b) Each of the Committees and the Executive Officers shall exercise its decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential of and financial returns from the Licensed Products in the Field in the Territory consistent with Commercially Reasonable Efforts and without regard to any other pharmaceutical product being developed or commercialized in the Field by or through a Party or any of its Affiliates (the "Collaboration Purpose"). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

3.2 Joint Steering Committee.

(a) Composition and Purpose. The JSC shall have overall responsibility for the oversight of the Collaboration. The purpose of the JSC shall be (i) to review and approve the overall strategy for an integrated worldwide Development program for each Licensed Product, including the Manufacture of Licensed Products in the Field for use in activities under the Plans and for the Commercialization of Licensed Products in the Field in the Territory; (ii) to review the efforts of the Parties in performing their responsibilities under the Plans and (iii) to oversee the Committees and resolve matters pursuant to the provisions of Section 3.11 below on which such Committees are unable to reach consensus. The JSC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). In addition, each Party shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Alliance Manager ("Alliance Manager") to the JSC. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among all Committees and providing single-point communication for seeking consensus both within the respective Party's organization and with the other Party's organization.

(b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the JSC shall in particular (i) annually review and approve the Global Development Plan(s) if any, Manufacturing Plan(s), Global Commercialization Plan(s) and Country/Region Commercialization Plan(s); (ii) at least semi-annually review the efforts of the Parties in performing their respective Development and Commercialization activities under the then-effective Plans; (iii) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point of communication for seeking consensus regarding key global strategy and Plan issues; (iv) establish sub-committees of the JSC, as the JSC deems appropriate and (v) consider and act upon such other matters as are specifically assigned to the JSC under this Agreement or otherwise agreed by the Parties.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3355

Samsung Bioepis Exhibit 1017, pg. 3355

3.3 Joint Development Committee.

(a) Composition and Purpose. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the worldwide Development of each Licensed Product in the Field; (ii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Global Development Plan(s) (and related Global Development Budget(s)) and (iii) to oversee the implementation of the Global Development Plan(s) and the Development operational aspects of the Collaboration. The JDC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) Specific Responsibilities. In particular, the JDC shall be responsible for:

(i) advising the JSC on the overall global Development strategy for each Licensed Product in the Field;

(ii) developing (or overseeing the development of), and updating at least annually, the Global Development Plan(s) (and related Global Development Budget(s)), as described in Sections 5.2 and 5.3, for final approval by the JSC;

(iii) reviewing and overseeing the implementation of, and compliance with, the Global Development Plan(s) (including the Global Development Budget(s));

(iv) developing forecasts for Clinical Supply Requirements to enable the timely preparation of the Manufacturing Plan;

(v) overseeing clinical and regulatory matters pertaining to Licensed Products in the Field arising from the Plans, and reviewing and approving protocols, statistical analysis plans, clinical study endpoints, clinical methodology and monitoring requirements for clinical trials of Licensed Products in the Field as contemplated under the Global Development Plan(s) and for Non-Approval Trials;

(vi) reviewing and approving proposed target Licensed Product labeling and reviewing and, to the extent set forth herein, approving proposed changes to product labeling with respect to Licensed Products in the Field in accordance with Section 7.2;

(vii) developing a target profile for each Licensed Product;

(viii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of Licensed Products in the Field;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3356

Samsung Bioepis Exhibit 1017, pg. 3356

(ix) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new formulations, delivery systems and improvements in concert with the JCC;

(x) establishing a regulatory Working Group responsible for overseeing, monitoring and coordinating the submission of Registration Filings in countries in the Territory, including coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with the Licensed Products in the Field;

(xi) establishing a Working Group responsible for overseeing all basic research activities for Licensed Products in the Field conducted under the Global Development Plan(s); and

(xii) considering and acting upon such other matters as specifically assigned to the JDC under this Agreement or by the JSC.

3.4 Joint Commercialization Committee.

(a) Composition and Purpose. The purpose of the JCC shall be to develop and propose to the JDC and JSC the strategy for the global Commercialization of Licensed Products in the Field in the Territory, and to oversee the implementation of the Global Commercialization Plans and the Commercialization operational aspects of the Collaboration on a country-by-country basis. The JCC shall be composed of at least two (2) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) JCC Responsibilities. In particular, the JCC shall be responsible for:

(i) developing and proposing to the JSC the global strategy for the Commercialization of each Licensed Product in the Field in the Territory;

(ii) commencing no later than two (2) years prior to the Anticipated First Commercial Sale anywhere in the Territory, (A) developing (or overseeing the development of), and updating not less frequently than once per Contract Year, the Global Commercialization Plan(s) and related Global Commercialization Budget(s) on a country-by-country basis for final approval by the JSC and (B) establishing, to the extent provided in Section 3.5, Country/Region Commercialization Committees to establish Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any updates thereto and carry out the other activities described in Section 3.5;

(iii) **********;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3357

Samsung Bioepis Exhibit 1017, pg. 3357

(iv) Establishing the trade dress for each Licensed Product, consistent with the guidelines established by the JCC, in the applicable Major Market Country;

(v) developing forecasts for Commercial Supply Requirements for the Territory to enable the timely preparation of the Manufacturing Plan(s) for review by the JMC and approval by the JSC;

(vi) for each Licensed Product, on a country-by-country basis for the Major Market Countries, developing and updating, as necessary, **********;

(vii) reviewing and overseeing compliance with the Global Commercialization Plan (including the related Global Commercialization Budget), and Country/Region Commercialization Plans (including the Country/Region Commercialization Budgets), to the extent applicable, for each Licensed Product, including ensuring that country specific launch plans are consistent with the Marketing Guidelines, and reviewing and validating latest annual estimates for the current calendar year compared to the Global Commercialization Budget and Country/Region Commercialization Budgets;

(viii) establishing or validating the number and position of Details required to meet market and sales forecasts and their conversion into the equivalent number of Detailing FTEs according to applicable weighting factors, based upon sales force and market practices, on a country-by-country basis, consistent, however, with the applicable Marketing Guidelines;

(ix) for each Licensed Product, selecting a Product Trademark in accordance with Section 11.2 and giving guidance on trade dress for such Licensed Product;

(x) determining the launch date for each Licensed Product on a country-by-country basis in Major Market Countries;

(xi) **********;

(xii) preparing short-term and long-term sales forecasts for each Licensed Product on a country-by-basis for Major Market Countries and reviewing such forecasts for the remaining countries;

(xiii) **********;

(xiv) validating the contents, design and layout of packaging for each Licensed Product in the Field;

(xv) validating plans and policies regarding journal and other publications with respect to each Licensed Product in the Field in concert with the JDC;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3358

Samsung Bioepis Exhibit 1017, pg. 3358

(xvi) formulating a life-cycle management strategy for each Licensed Product in the Field and evaluating new opportunities for new indications, formulations, delivery systems and improvements in concert with the JDC;

(xvii) matters relating to Regeneron's Commitment Level with respect to a Licensed Product in a Co-Commercialization Country, including consenting to changes therein; and

(xviii) considering and acting upon such other matters as specifically assigned to the JCC under this Agreement or by the JSC, JDC JFCor JMC.

3.5 Country/Region Commercialization Committees. The JCC will establish a Country/Region Commercialization Committee in each Major Market Country, and in each other Reporting Country/Region as and when determined by the JCC. The Country/Region Commercialization Committees will be responsible for establishing the Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any updates thereto with respect to the applicable Reporting Countries/Region(s). The Country/Region Commercialization Committees will also serve as a forum to consider and discuss and, if so empowered by the JCC, decide, in a more detailed and focused manner with respect to the applicable Reporting Countries/Region(s), and make suggestions or recommendations to the JCC with respect to, the matters referred to in Section 3.4, as applicable, including the implementation of decisions with respect thereto made by the JCC as contemplated by such Section 3.4.

3.6 Joint Finance Committee. The JFC shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including such specific responsibilities set forth in Article IX and such other responsibilities determined by the JSC. The JFC also shall respond to inquiries from the JDC, the JMC and the JCC, as needed.

3.7 Joint Manufacturing Committee. Working with the JDC and JCC, as appropriate, the Joint Manufacturing Committee shall be responsible for overseeing process development and Manufacturing activities, including preparing and updating the Manufacturing Plan for approval by the JSC and carrying out such other responsibilities set forth in Article VIII, process and technology selection, process improvements and related intellectual property filing strategy and obtaining a common process for manufacturing, recalls, market withdrawals, and any other corrective actions related to any Licensed Product in the Territory, and for any other matters specifically assigned to the JMC by the JSC. For process development activities, the Joint Manufacturing Committee shall consult the appropriate expert functions within both Parties or their Affiliates as appropriate.

3.8 Membership. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Sanofi. Each Party may replace its Committee members upon written notice to the other Party. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi. Each co-chairperson shall be

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3359

Samsung Bioepis Exhibit 1017, pg. 3359

entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of the meeting and prepare and issue final minutes within thirty (30) days thereafter.

3.9 Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than once every Quarter during the Term, commencing from and after the time such Committee is established as provided herein. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the Parties or their Affiliates) or when agreed by the Parties, by video or telephone conference. Other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of any Licensed Product in the Field (under obligations of confidentiality) may be invited by the Committee co-chairs to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least five (5) Business Days' prior written notice, except that emergency meetings may be called with at least two (2) Business Days' prior written notice.

3.10 Decision-Making. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on a Committee and leave decisions of such Committee(s) to representatives of the other Party.

3.11 Resolution of Governance Matters. As provided in Section 10.2, this Section 3.11 shall apply to matters constituting, or which if not resolved would constitute, a Governance Dispute.

(a) Generally. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible, provided that, in the case of any matter which cannot be resolved by the JDC, JCC, CRCC, JMC, JFC or other relevant Committee established hereunder, at the request of either Party, such matter shall promptly, and in any event within ten (10) Business Days (or two (2) Business Day in the event of an urgent matter) after such request, be referred to the JSC with a request for resolution.

(b) Referral to Executive Officers. In the event that the JSC is, after a period of five (5) Business Days from the date a matter is submitted to it for resolution pursuant to Section 3.11(a), unable to make a decision due to a lack of required unanimity, then either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3360

Samsung Bioepis Exhibit 1017, pg. 3360

good faith, attempt to resolve the referred dispute within five (5) Business Days of receiving such written notification, failing which, **********.

(c) Notwithstanding the foregoing, and subject to Section 10.4, Legal Disputes and disputes referred to in the third sentence of Section 2.6 (b) which involve a Technical Development Matter shall be referred to the Executive Officers with no Party's Executive Officer having final decision making authority.

(d) Interim Budgets. Pending resolution by the Executive Officers of any referred dispute under Section 3.11(b) and subject to the terms of Section 19.2, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets and plans to allow the Parties to continue to use Commercially Reasonable Efforts to Develop, Manufacture and Commercialize the Licensed Products in the Field in the Territory pursuant to this Agreement. The most recent Committee approved Plan(s) shall be extended pending approval by the Executive Officers of the interim budget(s) and Plan(s) referred to in this Section 3.11(c).

(e) Obligations of the Parties. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein. To the extent a Party performs any of its obligations hereunder through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder and thereunder for any failure of such performance, and each Party agrees that it will cause each of its Affiliates to comply with any provision of this Agreement which restricts or prohibits a Party from taking any specified action.

ARTICLE IV
LICENSE GRANTS

4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement (including, without limitation, Section 4.6) and any License to which Regeneron is a party, Regeneron hereby grants to Sanofi (a) the nontransferable (except as permitted by Section 20.9), co-exclusive (with Regeneron and its Affiliates) right and license under the Regeneron Intellectual Property to make, have made, use, develop and import Licensed Products for use in the Field in the Territory, and (b) the nontransferable (except as permitted by Section 20.9), exclusive (except as otherwise provided below in this Section 4.1) right and license under the Regeneron Intellectual Property to sell and offer to sell Licensed Products in the Field in the Territory, except that the right and license granted pursuant to this clause (b) shall be co-exclusive (with Regeneron and its Affiliates) to the extent of Regeneron's right to Co-Promote Licensed Products and Regeneron's right to supply Licensed Products to Sanofi, as contemplated by this Agreement. Sanofi will have the right to grant sublicenses under the foregoing license only as set forth in Section 4.4.

4.2 Sanofi License Grants. Subject to the terms and conditions of this Agreement and any License to which Sanofi or any of its Affiliates is a party, Sanofi hereby grants to Regeneron the nontransferable (except as permitted by Section 20.9), royalty-free, co-

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3361

Samsung Bioepis Exhibit 1017, pg. 3361

exclusive (with Sanofi and its Affiliates) right and license under the Sanofi Intellectual Property to the extent necessary to make, have made, use, develop and import Licensed Products for use in the Field in the Territory and to Co-Promote Licensed Products to the extent provided in this Agreement.

4.3 Newly Created Intellectual Property. In addition to the other licenses granted under this Article IV and subject to the other terms and conditions of this Agreement, to the extent permitted under any relevant Third Party agreement, each Party grants to the other Party and its Affiliates the perpetual, royalty-free, paid-up, non-exclusive, worldwide right and license, with the right to grant sublicenses, to use and practice for any and all purposes: all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights), other than Know-How jointly owned pursuant to Section 12.1(e) and other than Excluded Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the Effective Date directly in connection with the performance of the research and clinical activities approved by the JDC, in each case, as included in the Global Development Plans. As used above, the term "Excluded Rights" shall mean any Patents or Know-How claiming or covering composition (including any formulation) of a Licensed Product. For the avoidance of doubt, nothing in this Section 4.3 shall be construed to grant either Party any license to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities approved by the JDC and/or the clinical development activities approved by the JDC, in each case, as included in Global Development Plans.

4.4 Sublicensing. Unless otherwise restricted by any License, Sanofi will have the right to sublicense any of its rights under the first sentence of Section 4.1 only with the prior written consent of Regeneron, such consent not to be unreasonably withheld or delayed with respect to rights outside the Major Market Countries (and only with the prior written consent of Regeneron, which consent may be withheld for any reason, in the Major Market Countries), except that Sanofi may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Regeneron's consent. Unless otherwise restricted by any License, Regeneron will have the right to sublicense any of its rights under Section 4.2 with the prior written consent of Sanofi, such consent not to be unreasonably withheld or delayed, except that Regeneron may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Sanofi's consent. Each Party shall remain responsible and liable for the compliance by its Affiliates and Sublicensees with applicable terms and conditions set forth in this Agreement. Any such sublicense agreement will require the Sublicensee of a Party to comply with the obligations of such Party as contained herein, including, without limitation, the confidentiality and non-use obligations set forth in Article XVI, and will include, with respect to a Sublicensee of Sanofi, an obligation of the Sublicensee to account for and report its sales of Licensed Products to Sanofi on the same basis as if such sales were Net Sales by Sanofi. For the avoidance of doubt, Regeneron shall be entitled to receive its share of the applicable Profit Split based on Net Sales of Licensed Products sold by Sublicensees under this Agreement. In the event of a breach by a Sublicensee of any sublicense agreement which has or is reasonably likely to have an adverse effect on either Party or any of its Affiliates or any Party's Intellectual Property, then the harmed Party may cause the other Party or its Affiliate to exercise, and the other Party or its Affiliate will promptly exercise, any termination rights it may have under the sublicense with the Sublicensee. Any

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3362

Samsung Bioepis Exhibit 1017, pg. 3362

sublicense agreement will provide for the termination of the sublicense or the conversion of the sublicense to a license directly between the Sublicensee and the other Party, at the option of the other Party, upon termination of this Agreement. Furthermore, any such sublicense shall prohibit any further sublicense or assignment. Each Party will forward to the other Party a complete copy of each applicable fully executed sublicense agreement (and any amendment(s) thereto) within ten (10) days of the execution of such agreement.

4.5 No Implied License. Except as expressly provided in this Article IV or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.

4.6 Retained Rights. With respect to the licenses granted under this Article IV, and for the avoidance of doubt, Regeneron expressly reserves for itself and its Affiliates and Third Party licensees under the Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions, the right to Manufacture and to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the further avoidance of doubt, Regeneron retains all rights in Regeneron Intellectual Property, Regeneron's interest in the Joint Inventions and Licensed Products not expressly licensed hereunder, including, without limitation the right to exploit Regeneron Intellectual Property and Regeneron's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field. With respect to the licenses granted under this Article IV, and for the avoidance of doubt, Sanofi expressly reserves for itself and its Affiliates and Third Party licensees under the Sanofi Intellectual Property and Sanofi's interest in the Joint Inventions, the right to Manufacture and to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the avoidance of doubt, Sanofi retains all rights in Sanofi Intellectual Property, Sanofi's interest in the Joint Inventions and Licensed Products not expressly licensed hereunder, including, without limitation, the right to exploit Sanofi Intellectual Property and Sanofi's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field.

ARTICLE V
DEVELOPMENT ACTIVITIES

5.1 Development of Licensed Products. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to Licensed Products in the Field pursuant to the Global Development Plans under the general direction and oversight of the JDC. Each Party shall use Commercially Reasonable Efforts to Develop Licensed Products in the Field, carry out the Development activities assigned to it in Development Plans in a timely manner and conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices.

5.2 Global Development Plans. With respect to each Licensed Product, the JDC shall prepare and present a Global Development Plan for approval by the JSC, and the JSC shall approve a Global Development Plan for such Licensed Product, within three (3) months after the time such Licensed Product first becomes a Licensed Product in accordance with the terms of the Discovery Agreement and this Agreement, and shall, subject to the further provisions of this Section 5.2, determine which Party will take the lead in the Development of

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3363

Samsung Bioepis Exhibit 1017, pg. 3363

such Licensed Product. Prior to such JSC approval of the first Global Development Plan for any Licensed Product, the Parties shall Develop the Licensed Product in accordance with the applicable Initial Development Plan, including, in the case of REGN88 (IL-6RmAb), a summary outline of an Initial Development Plan attached hereto as Exhibit B. An updated Global Development Plan for such Licensed Product will be presented by the JDC for approval by the JSC, and approved by the JSC, at least two (2) months prior to the end of each Contract Year. Each Global Development Plan for a Licensed Product will set forth the plan for Development of such Licensed Product in the Field over at least three (3) Contract Years and will include (a) strategies and timelines for Developing and obtaining Approvals for such Licensed Product in the Field in the Territory, and (b) the allocation of responsibilities for Development activities between the Parties, and/or Third Party service providers. Each Global Development Plan will be reviewed and informally updated by the JDC not less frequently than once every six (6) months for the ensuing three (3) year period. Unless and to the extent otherwise agreed by the Parties with respect to a particular Licensed Product, (i) the Parties shall alternate, on a Licensed Product-by-Licensed Product basis, in being allocated principal responsibility for formulating, and carrying out, the principal Development activities for the applicable Licensed Product under the applicable Global Development Plan(s) from the time the applicable Product Candidate is advanced into Development in accordance with the Discovery Agreement (whereupon such Product Candidate automatically constitutes a Licensed Product) through proof of concept as defined in the Global Development Plan for the Licensed Product (the "POC Time") (with respect to any Licensed Product, the Party with such principal responsibility through the POC Time being referred to as the "POC Principal Party") and (ii) the Parties shall alternate being allocated principal responsibility for formulating, and carrying out, all clinical trials conducted subsequent to the POC Time for the applicable Licensed Product(s) under the applicable Global Development Plan(s) (with respect to a Licensed Product, the Party with such principal responsibility being referred to as the "Post-POC Principal Party"), with Sanofi being the Post-POC Principal Party for two (2), and Regeneron being the Post-POC Principal Party for one (1), out of each three (3) Licensed Products. The Parties shall cause their respective representatives on the JDC and the JSC, in preparing, updating and approving Global Development Plans, to allocate principal Development responsibilities thereunder as provided in this Section 5.2.

5.3 Global Development Budgets. Each Global Development Plan for a Licensed Product shall include a related Global Development Budget (each individually, a "Global Development Budget" and collectively, "Global Development Budgets") and each Global Development Budget shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Global Development Plan of which such Global Development Budget is a part in accordance with this Agreement. Amendments and updates to any Global Development Budget shall not be effective without the approval of the JSC.

5.4 Development Reports. Within forty-five (45) days after the end of each Quarter, commencing in the first Quarter in which Development activities commence hereunder with respect to the first Licensed Product, Regeneron and Sanofi shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Quarter in connection with each Global Development Plan, together with a statement of Development Costs incurred by such Party during such Quarter, which statement shall detail those amounts to be included in the Consolidated Payment Report for such Quarter

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3364

Samsung Bioepis Exhibit 1017, pg. 3364

and shall be in such form, format and of such level of detail as approved by the JFC. At the next JSC meeting held following such forty-five (45) day period, the JSC will approve the final Development Costs which will be used in calculating the Global Development Balance.

5.5 Review of Clinical Trial Protocols. The JDC will establish procedures for the expeditious review of clinical trial protocols for the Licensed Products submitted to the JDC by Regeneron pursuant to Section 2.6(b), including, without limitation, pre-approval authorizations for Non-Approval Trials.

5.6 Regeneron Early Development Opt-Out. Within thirty (30) days of the date that Sanofi exercises its Opt-In Rights with respect to any Licensed Product thereby including such Licensed Product under this Agreement, Regeneron shall have a one-time right to opt-out of the further Development of such Licensed Product (such right of Regeneron, the "Regeneron Early Development Opt-Out Right", and each such Licensed Product as to which Regeneron has exercised the Regeneron Early Development Opt-Out Right, an "Early Development Opt-Out Product") by delivering written notice of such opt-out (a "Regeneron Early Opt-Out Notice") to Sanofi. Effective immediately upon the delivery by Regeneron to Sanofi of a Regeneron Early Opt-Out Notice with respect to a Licensed Product, (i) such Licensed Product shall automatically constitute an Early Development Opt-Out Product, (ii) the rights and licenses granted by Regeneron to Sanofi hereunder with respect to such Early Development Opt-Out Product shall automatically terminate, (iii) Sanofi and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than for amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or the Collaboration by Regeneron), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Regeneron Intellectual Property existing at the time the Regeneron Early Opt-Out Notice was delivered to Sanofi, to Develop, Manufacture and Commercialize in the Field in the Territory (and solely to the extent that such Regeneron Intellectual Property has, as of the date of the Regeneron Early Opt-Out Notice, actually been incorporated into such Early Development Opt-Out Product or otherwise claims or covers its use) the Early Development Opt-Out Product with respect to which such Regeneron Early Development Opt-Out Notice was delivered, (iv) **********, (v) Regeneron shall, as promptly as reasonably practicable, transfer to Sanofi all clinical activities related to the Early Development Opt-Out Product, (vi) except as set forth in this Section 5.6, Regeneron shall have no further rights or obligations with respect to such Early Development Opt-Out Product, (vii) Sanofi shall be free to Develop and Commercialize such Early Development Opt-Out Product in the Field in the Territory free of any obligations to Regeneron hereunder, except for reimbursing Regeneron for any pass through costs to Third Party licensors of Regeneron Intellectual Property, to the extent attributable to the Development or Commercialization of Licensed Products by Sanofi, and (viii) **********. As used in clause (viii) immediately above, "antibody" shall mean any actual or potential therapeutic or diagnostic antibody (whether fully human, humanized, phage display, chimeric, polyclonal, or any other type of antibody), or any derivative, or fragment thereof, including any immunoconjugates or fusions comprising any such gene product, derivative or fragment, and any composition or formulation that incorporates or includes any of the foregoing. Except as provided in this Section 5.6, a Party's obligations under this Agreement with respect to the Development of a Licensed Product shall terminate only upon termination of this Agreement

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3365

Samsung Bioepis Exhibit 1017, pg. 3365

with respect to such Licensed Product or in its entirety in accordance with, and only to the extent and upon the terms and conditions set forth in, Article XIX.

ARTICLE VI
COMMERCIALIZATION

6.1 Commercialization of Licensed Products in the Field in the Territory. Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to Licensed Products in the Field in the Territory under the direction and oversight of the JCC. Sanofi shall be the lead Party with respect to the Commercialization of Licensed Products in the Field. Sanofi shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field, and carry out the Commercialization activities in accordance with the applicable Global Commercialization Plan and the applicable Country/Region Commercialization Plans in a timely manner and conduct all such activities in compliance with applicable Laws. Except as otherwise provided in this Agreement, Sanofi shall bear all costs and expenses to Commercialize the Licensed Products in the Field in the Territory. Sanofi or its Affiliate shall invoice and book all sales of the Licensed Products in the Field in the Territory and shall appropriately record all such sales. Sanofi or its Affiliate shall also be responsible for the distribution of the Licensed Products in the Field in the Territory and for paying all governmental rebates which are due or owing with respect to the Licensed Products in the Field in the Territory. Commencing with the initiation of Phase 3 Trials for a Licensed Product in the Field in the Territory, the Parties will commence regular ad hoc discussions concerning the Commercialization strategy for the Licensed Product.

6.2 Global Commercialization Plan(s). Each Global Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. Each Global Commercialization Plan shall be prepared by Sanofi (with assistance from Regeneron) at the direction of the JCC, and submitted to the JCC for review and approval. Once approved by the JCC, a Global Commercialization Plan will be presented to the JSC for review and approval at least **********. Such Global Commercialization Plan for each subsequent Contract Year shall be updated by the JCC and approved by the JSC at least one (1) month prior to the end of the then current Contract Year. The Global Commercialization Plan with respect to each Licensed Product shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

(a) the overall global strategy for Commercializing such Licensed Product in the Field in the Territory, including target product profiles, branding, positioning, promotional materials and core messages for such Licensed Product;

(b) **********;

(c) the related Global Commercialization Budget;

(d) anticipated launch dates for such Licensed Product for Major Market Countries;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3366

Samsung Bioepis Exhibit 1017, pg. 3366

(e) market and sales forecasts for such Licensed Product in the Field in the Territory in a form to be agreed between the Parties;

(f) strategies for the detailing and promotion of such Licensed Product in the Field in the Territory;

(g) anticipated major advertising, public relations and patient advocacy programs for such Licensed Product in the Field in the Territory;

(h) Non-Approval Trials; and

(i) all other Marketing Guidelines.

6.3 Country/Region Commercialization Plans. Each Country/Region Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. It is anticipated that each Country/Region Commercialization Plan for each Licensed Product will be prepared by Sanofi (with assistance from Regeneron in the U.S. and all Co-Commercialization Countries), and approved by the JCC, at least **********. Such Country/Region Commercialization Plan for each subsequent Contract Year shall be updated by the applicable Country/Region Commercialization Committee, and approved by the JCC, at least two (2) months prior to the end of the then current Contract Year. Each Country/Region Commercialization Plan with respect to each Licensed Product shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including the overall strategy for Commercializing such Licensed Product, **********, market and sales forecasts, and estimated FTE and Shared Commercial Expenses. In those countries where the Parties are Co-Promoting a Licensed Product, such Country/Region Commercialization Plans shall include more detailed information on the coordination of detailing and promotional efforts, including the estimated number of detailing FTEs for each Party (based on the number and position of Details required to meet the market and sales forecasts) and the specific allocation of Co-Promotion efforts between the Parties.

6.4 Commercialization Efforts; Sharing of Commercial Information.

(a) Sanofi (through its Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory in accordance with the Global Commercialization Plans, the Marketing Guidelines and, as applicable, the Country/Region Commercialization Plan(s). Without limiting the generality of the foregoing, (i) Sanofi will, as necessary, build, train and apply a field force necessary to Commercialize the Licensed Products in the Field in accordance with the applicable Global Commercialization Plans and Country/Region

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3367

Samsung Bioepis Exhibit 1017, pg. 3367

Commercialization Plans, (ii) Sanofi's, and in the Co-Commercialization Countries each Party's, sales representatives shall provide the FTE effort and detail the Licensed Products in the Field in accordance with the approved Country/Region Commercialization Plan (if applicable), Global Commercialization Plan(s) and all applicable Laws.

(b) Sanofi will provide Regeneron with full access to material information directly relating to the Commercialization of each Licensed Product in the Field, including, without limitation, information relating to anticipated launch dates, key market metrics, market research, and sales. Without limiting the foregoing, beginning in the Quarter of the First Commercial Sale in each Major Market Country, Sanofi will provide Regeneron, and with respect to each Co-Commercialization Country, Regeneron will provide Sanofi, on a quarterly basis, with reports of the activity within its field force in each such Major Market Country, which will include reasonable data from reports created by Sanofi or Regeneron for its internal management purposes.

(c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the Licensed Products in the Field, Licensed Product quality complaints and similar information.

(d) No Party may initiate or support any Non-Approval Trial for a Licensed Product in the Field in the Territory without the prior approval of the JDC.

6.5 Co-Commercialization of Licensed Products.

(a) Exercise of Co-Promote Option by Regeneron. In the event that Regeneron desires to Co-Promote a Licensed Product in a particular country, Regeneron shall notify Sanofi of (i) its preliminary indication of intent regarding such Co-Promotion of such Licensed Product at least ********** and (ii) its final decision regarding whether to Co-Promote such Licensed Product in such country at **********. If Regeneron does not timely notify Sanofi of its preliminary indication or of its final decision within the periods set forth in clause (i) or (ii) above, as applicable, Regeneron shall not be entitled to exercise its option to Co-Promote such Licensed Product in such country until on or after the **********.

(b) Co-Commercialization. Sanofi and Regeneron (through their respective Affiliates where appropriate) shall Co-Commercialize Licensed Products under the applicable Product Trademarks in each Co-Commercialization Country in accordance with the then-current and applicable Country/Region Commercialization Plan. Each Party shall use, or shall cause its local Affiliates to use, Commercially Reasonable Efforts to Co-Commercialize the Licensed Products in the Co-Commercialization Countries, and carry out the activities assigned to it in the applicable Country/Region Commercialization Plan. Each Party shall ensure that its Co-Commercialization activities conform with the parameters in the applicable approved Country/Region Commercialization Plan and the applicable Global Commercialization Plan.

(c) Decision to Discontinue Co-Commercialization. In the event that Regeneron decides it no longer wishes to Co-Commercialize a Licensed Product in a

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3368

Samsung Bioepis Exhibit 1017, pg. 3368

particular Co-Commercialization Country or does not wish to maintain its minimum sales force FTE requirement for Co-Commercialization of such Licensed Product in such Co-Commercialization Country, provided that Regeneron has Co-Commercialized Licensed Product and maintained its minimum sales force FTE requirement for ********** in such Co-Commercialization Country from the date it commences Co-Promoting in such Co-Commercialization Country, Regeneron must give the JCC and Sanofi ********** prior written notice of such decision. At the end of such ********* period, Regeneron shall cease all Co-Commercialization activities with respect to such Licensed Product in such Co-Commercialization Country. **********.

(d) Field Force Coordination. The JCC or the applicable Committee shall coordinate the Co-Promotion of each Licensed Product by Sanofi, Regeneron, their respective local Affiliates and their respective sales representatives in each Co-Commercialization Country. The Parties will cooperate in the conduct of such activities with respect to scheduling, geographical allocation, and Professional or other customer targeting in order to optimize profits under the applicable Country/Region Commercialization Plan. Without limiting the generality of the foregoing, in each Co-Commercialization Country the Parties will share and, to the extent appropriate, cooperate to implement consistent policies and procedures with respect to the manner in which details and other sales visits are conducted.

(e) Co-Commercialization FTE Efforts.

(i) FTE Efforts. Upon the exercise of its election pursuant to Section 6.5(a) to Co-Promote in a country, Regeneron will provide to Sanofi a binding notice of the FTE effort that Regeneron commits to deliver in Co-Promoting such Licensed Product in such country during the first (1st) Contract Year for which Regeneron exercised its right to Co-Promote (the "Regeneron Commitment Level"). Subject to the provisions of Section 6.4(e)(ii), if Regeneron elects to Co-Promote a Licensed Product in a country, in no event shall the Regeneron Commitment Level be less than ********** of the total anticipated FTE effort by both Parties (taken together) in Co-Promoting such Licensed Product in such Co-Commercialization Country, unless otherwise agreed by the Parties. Such FTE effort shall be based upon the forecasted number and position of Details required to meet the market and sales forecasts in such Co-Commercialization Country, and their conversion (by the JCC or applicable Country/Region Commercialization Committee) into the equivalent number of Detailing FTEs according to applicable weighting factors, based upon the sales force and marketing practices in such Co-Commercialization Country. In no event shall the Regeneron Commitment Level in Co-Promoting such Licensed Product in such Co-Commercialization Country exceed ********** of the anticipated total FTE effort by both Parties in Co-Promoting such Licensed Product in such Co-Commercialization Country or such other maximum percentage agreed by the Parties (the "Maximum Regeneron Effort"). Regeneron's binding notice referred to above in this Section 4 (e)(i) shall be accompanied by a plan (which shall be developed by Regeneron in cooperation

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3369

Samsung Bioepis Exhibit 1017, pg. 3369

with Sanofi and shall be intended to coordinate and integrate the Parties' respective FTE efforts and detailing activities) for ensuring that Regeneron will have in place a field force of qualified sales representatives to satisfy the Regeneron Commitment Level. In each Co-Commercialization Country, Sanofi shall perform the anticipated total FTE effort above the Regeneron Commitment Level.

(ii) Ophthalmology. In the event that a Licensed Product receives Marketing Approval for an Indication related to ophthalmology, then, at Regeneron's option, Regeneron shall have the lead in the promotion of such Licensed Product in such Indication, provided, however, that the limitations set forth in Section 6.5(e)(i) shall apply.

(f) Training. The Parties will coordinate sales force training efforts in Co-Commercialization Countries and will share training materials (and conduct joint training, where appropriate) to facilitate joint sales force training efforts.

(g) Samples. Sanofi shall provide Regeneron with Licensed Product samples for use in Co-Commercialization Countries as required in the applicable Country/Region Commercialization Plan. Sanofi and Regeneron (and their respective Affiliates) shall use samples strictly in accordance with the then-applicable approved Country/Region Commercialization Plan and shall store and distribute samples in compliance with applicable Laws. Each Party (and its local Affiliates) will maintain those records required by all applicable Laws and shall allow representatives of the other Party to inspect such records and storage facilities for the Licensed Product samples on request.

6.6 Licensed Product Pricing and Pricing Approvals in the Territory. **********.

6.7 Sales and Licensed Product Distribution in the Territory; Other Responsibilities.

(a) Sanofi (or its Affiliate) shall invoice and book, and appropriately record, all sales of the Licensed Products in the Field in the Territory. Sanofi (or its Affiliate) also shall be responsible for (i) the distribution of Licensed Products in the Field in the Territory and for paying all governmental rebates which are due and owing with respect to the Licensed Products in the Field in the Territory, (ii) handling all returns of Licensed Product sold under this Agreement and (iii) handling all aspects of ordering, processing, invoicing, collection, distribution and receivables with respect to Licensed Products in the Field in the Territory.

(b) Sanofi (through its local Affiliates where appropriate), and with respect to the Co-Commercialization Countries, Regeneron (through its local Affiliates where appropriate), shall maintain records relating to its sales representative FTEs for the Licensed Products in the Field in the countries in a manner sufficient to permit the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3370

Samsung Bioepis Exhibit 1017, pg. 3370

determination of Sales Force Cost and Medical Post-Approval Cost and the incentive compensation requirements set forth in the Marketing Guidelines.

6.8 Contract Sales Force. Each Party shall be entitled to engage a Contract Sales Force for up to ********* of such Party's Sales Force utilized for any Licensed Product to discharge its annual FTE effort with respect to Commercialization of such Licensed Product, provided that in the event that Regeneron discontinues Co-Commercialization in a particular Co-Commercialization pursuant to Section 6.5(c), then Sanofi shall be entitled to engage a Contract Sales Force for more than ********** for that Co-Commercialization Country. If a Party (or its local Affiliate) retains a Contract Sales Force, that Party (or its local Affiliate) will be responsible for (i) all costs associated with retaining such Contract Sales Force above approved Sales Force Costs included in the applicable Country/Region Commercialization Budget and for the Contract Sales Force's compliance with this Agreement, including, without limitation, the training and monitoring of such Contract Sales Force and ensuring compliance with all applicable Laws, and (ii) ensuring that sales representatives in such Contract Sales Force have minimum skill levels customary for sales representatives in major pharmaceutical companies in such country in the relevant therapeutic area.

6.9 Promotional Materials.

(a) Except as provided in and subject to Section 6.9(b): Sanofi will be responsible, consistent with the Marketing Guidelines, the Global Commercialization Plan and the Country/Region Commercialization Plans (as applicable) and the decisions of the JCC with respect to Promotional Materials as contemplated by Section 3.4(b)(vi), for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the Territory, except where Regeneron shall perform such responsibilities as the Lead Regulatory Party. Upon request, Regeneron will have the right to review and comment on all major Promotional Materials for use in any country in the Territory prior to their distribution by Sanofi for use in the Territory.

(b) The Parties and their Affiliates shall only use the Promotional Materials and only conduct marketing and promotional activities for the Licensed Products which, in each case, are approved by the JCC or the applicable Country/Region Commercialization Committee if so delegated by the JCC for the applicable Major Market Country. Sanofi shall ensure that Regeneron's sales representatives are provided with reasonable quantities of Promotional Materials for use in a Co-Commercialization Country consistent with the Regeneron Commitment Level for such Co-Commercialization Country in accordance with the applicable approved Country/Region Commercialization Plan. All Promotional Materials generated for a Co-Commercialization Country shall be maintained in confidence and shall not be disclosed or distributed to Third Parties, until such time as they have been reviewed and approved as set forth in this Section.

(c) Sanofi shall own all rights to all Promotional Materials, including all copyrights thereto, in the Major Market Countries.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3371

Samsung Bioepis Exhibit 1017, pg. 3371

6.10 Promotional Claims/Compliance. Neither Party nor any of its Affiliates shall make any medical or promotional claims for any Licensed Product in the Field other than as permitted by applicable Laws. When distributing information related to any Licensed Product or its use in the Field in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), each Party and its Affiliates shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country.

6.11 Restriction on Bundling in the Territory. If Sanofi or its Affiliates or Sublicensees sell a Licensed Product in the Field in the Territory to a customer who also purchases other products or services from any such entity, Sanofi agrees not to, and to require its Affiliates and Sublicensees not to, bundle or include any Licensed Product as part of any multiple product offering or discount or price the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by a Party or its Affiliates to such customer, (b) is inconsistent with the Collaboration Purpose or (c) would result in pricing and discounting inconsistent with the applicable Marketing Guidelines.

6.12 Inventory Management. Sanofi shall use Commercially Reasonable Efforts to manage Licensed Product inventory on hand at wholesalers and Sublicensees so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.

6.13 Medical and Consumer Inquiries. The JCC shall establish guidelines to handle medical questions or inquiries from consumers relative to Licensed Products.

6.14 Market Exclusivity Extensions. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) a Party(ies) has the exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to Commercialize a Licensed Product in the Field in such country and (b) no generic equivalent of a Licensed Product in the Field may be marketed in such country.

6.15 Post Marketing Clinical Trials. Subject to the provision of this Agreement, the Parties shall comply with any clinical trials obligations with respect to a Marketing Approval with respect to any Licensed Product use in the Field in any country in the Territory, imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

ARTICLE VII
CLINICAL AND REGULATORY AFFAIRS

7.1 Ownership of Approvals and Registration Filings.

(a) Unless otherwise agreed to by the Parties, the Post-POC Principal Party shall be the Lead Regulatory Party and shall own (i) all Approvals with respect to Licensed Product in the Territory and (ii) the IND for Licensed Products during such time

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3372

Samsung Bioepis Exhibit 1017, pg. 3372

as it is the Post-POC Principal Party and shall have the rights and obligations set forth in Sections 7.2 to 7.4 (inclusive) with respect thereto. **********.

(b) The Lead Regulatory Party shall license, transfer, provide a letter of reference with respect to, or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.

(c) The non-Lead Regulatory Party shall provide such assistance with respect to regulatory matters as is reasonably requested by the Lead Regulatory Party and consistent with the terms of this Agreement.

7.2 Regulatory Coordination.

(a) The Lead Regulatory Party shall oversee, monitor and coordinate applicable regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to each Licensed Product in the Field in each jurisdiction as to which it is the Lead Regulatory Party; provided that it shall adhere to the obligations in this Article VII. Without limiting the foregoing, the Lead Regulatory Party will be responsible for, and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for each Licensed Product in the Field for which it has responsibility as the Lead Regulatory Party. To the extent applicable, the Lead Regulatory Party shall perform all such activities in accordance with the Plans and all applicable Laws.

(b) The Parties shall establish procedures, through the JDC or the JCC, to ensure that the Parties exchange on a timely basis all necessary information to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field, including, without limitation, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities and (ii) to comply with Laws in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field anywhere in the Territory. The Parties shall provide to each other prompt written notice of any Approval of a Licensed Product in the Field anywhere in the world. The Parties shall work together cooperatively through the JDC in the preparation of regulatory strategies and with respect to all material regulatory actions, communications and Regulatory Filings for Licensed Products in the Field in the Territory.

(c) The Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party as promptly as practicable with written notice and copies of any material (i) draft filings with, (ii) submissions to and (iii) correspondence (including Approvals) with, Regulatory Authorities pertaining to the Development and/or Commercialization of a Licensed Product in the Field under the Plans, and shall use reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such material filings and submissions (including,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3373

Samsung Bioepis Exhibit 1017, pg. 3373

without limitation, all annual and periodic safety reports for Licensed Products in the Field), and consistent with applicable laws, to have up to two (2) representatives from the other Party attend and actively participate in all material, pre-scheduled meetings, telephone conferences and/or discussions with Regulatory Authorities to the extent such material meetings, telephone conferences and/or discussions pertain to the Development and/or Commercialization of any Licensed Product in the Field. Without limiting the foregoing, the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party on a timely basis with all material information, data and materials reasonably necessary for the other Party to participate in the preparation of the material filings and submissions referred to in this paragraph (c), said items to be provided to the other Party in a timely manner. The Parties will discuss in good faith any disputes on the contents of filings or submissions referred to in this paragraph (c) to the Regulatory Authorities and disputes shall be submitted to the JDC for timely resolution.

(d) For each Licensed Product, the JDC shall develop and the JSC shall approve proposed target Licensed Product labeling ("Target Labeling") for use in the Territory.

7.3 Regulatory Events. Each Party shall keep the other Party informed, commencing within forty-eight (48) hours after notification (or other time period specified below), of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority, which:

(a) raises any material concerns regarding the safety or efficacy of any Licensed Product in the Field;

(b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of a Licensed Product in the Field under the Plans; provided, however, that each Party shall inform the other Party of the foregoing no later than twenty-four (24) hours after receipt of a notification referred to in this clause (b); or

(c) is reasonably likely to lead to a recall or market withdrawal of any Licensed Product in the Field anywhere in the Territory.

Information that shall be disclosed pursuant to this Section 7.3 shall include, but not be limited to the following matters with respet to Licensed Products:

(i) Governmental Authority inspections of Manufacturing, Development, distribution or other facilities;

(ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities, in each case, to the extent involving matters described in clauses (a), (b) or (c) of this Section 7.3;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3374

Samsung Bioepis Exhibit 1017, pg. 3374

(iii) receipt of a warning letter issued by a Regulatory Authority;

(iv) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction; and

(v) receipt of product complaints concerning actual or suspected Licensed Product tampering, contamination, or mix-up (e.g., wrong ingredients).

7.4 Pharmacovigilance and Product Complaints. While the Lead Regulatory Party shall be responsible for managing pharmacovigilance and product complaints and for formulating and implementing any related strategies, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning pharmacovigilence and risk management plans and product complaint reporting in all countries in which any Licensed Product is being developed, manufactured, or commercialized anywhere in the Territory. Without limitation to the foregoing, the Parties shall execute a Safety Data Exchange Agreement ("SDEA") setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse events/adverse drug reactions and Licensed Product complaints to ensure timely communication to Regulatory Authorities and compliance with Laws.

7.5 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a Licensed Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit to the extent it relates to the Development, Manufacture or Commercialization of a Licensed Product for use in the Field under this Agreement. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will promptly provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses; provided that the other Party, to the extent practicable, shall have the right to review and comment on such responses to the extent they cover or may be reasonably expected to adversely impact the Licensed Products in the Field in the Territory, and the Party that received the observations shall consider in good faith the comments made by such other Party. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within forty-eight (48) hours of receipt of a notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities used or proposed to be used for the Manufacture of Licensed Products for use in the Field under this Agreement; provided that such notification shall be given no later than twenty-four (24) hours prior to any such Regulatory Authority audit or inspection.

7.6 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to any Licensed Product in the Field in the Territory shall be made only upon mutual agreement of the Parties, which agreement shall not be unreasonably withheld or delayed; provided, however, that nothing herein shall prohibit either

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3375

Samsung Bioepis Exhibit 1017, pg. 3375

Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or Law. The Party that determines that a recall or market withdrawal of a Licensed Product in the Field in the Territory may be required shall, within twenty-four (24) hours, notify the other Party and, without limitation of and subject to the proviso in the immediately preceding sentence, the Parties shall decide whether such a recall or market withdrawal is required. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal. Expenses associated with such recalls will be treated as Other Shared Expenses.

ARTICLE VIII
MANUFACTURING AND SUPPLY

8.1 Manufacture and Supply of Clinical Supply Requirements of Formulated Bulk Product. Until such time as Commercial Supply Requirements are being Manufactured, Regeneron will use Commercially Reasonable Efforts to provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements of Licensed Products in the Field in the Territory in accordance with the Manufacturing Plan. Regeneron may use its Manufacturing facilities or, subject to Sanofi's prior written approval, such approval not to be unreasonably withheld or delayed, Sanofi or Third Parties to Manufacture such Formulated Bulk Product. If an entity other than Regeneron is to be used to Manufacture Formulated Bulk Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to Manufacture the applicable Licensed Product in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Party Manufacturers. The Formulated Bulk Product Manufactured by or on behalf of Regeneron for Clinical Supply Requirements will be billed to Sanofi by Regeneron at the Manufacturing Cost per Part I of Schedule 1 as a Development Cost. To the extent that Regeneron maintains manufacturing capacity available for the Manufacture of Clinical Supply Requirements, the cost of maintaining such capacity shall be included as a Development Cost to the extent it is not included as a Manufacturing Cost.

8.2 Finished Product Supply of Clinical Supply Requirements. Regeneron will timely identify, and enter into an agreement with, a Third Party or Third Parties or Sanofi (or use its own facilities, if Regeneron has such capabilities) to perform the filling, packaging, labeling and testing of the Formulated Bulk Product and supply Finished Product for Clinical Supply Requirements for Licensed Products for use under this Agreement. If an entity other than Regeneron is to be used to perform filling, packaging, labeling or testing services related to Finished Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to perform such services in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Parties. Such Finished Product for Clinical Supply Requirements Manufactured on behalf of Regeneron will be billed to Sanofi at the Manufacturing Cost as a Development Cost, in accordance with Part I of Schedule 1.

8.3 Manufacture and Supply of Commercial Supply Requirements.

(a) The Parties, through the JMC and JSC, will determine whether a Party, or a Third Party on behalf of a Party, will be responsible for Manufacturing and

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3376

Samsung Bioepis Exhibit 1017, pg. 3376

supplying Commercial Supply Requirements of Formulated Bulk Product and/or Finished Product for each Licensed Product for use under this Agreement. The JMC shall use all reasonable efforts to make such determination no later than **********. Such a notice (a "Manufacturing Notice") shall be irrevocable and shall be treated as a firm commitment to supply such Formulated Bulk Product or Finished Product, as the case may be. Preference will be given to having a Party or both Parties, rather than Third Parties, Manufacture and supply Commercial Supply Requirements, provided that the Party is qualified to Manufacture such Licensed Product in accordance with applicable Good Practices and on terms mutually acceptable to the Parties. If both Parties desire to Manufacture and supply such Commercial Supply Requirements, **********. If one Party desires to Manufacture and supply **********. If the Parties can not agree on terms under which either or both Parties will Manufacture and supply Commercial Supply Requirements of a Licensed Product, the JMC shall arrange for a Third Party to Manufacture and supply such Commercial Supply Requirements.

(b) Once Manufacture of Commercial Supply Requirements of a Licensed Product begins, or is scheduled to begin, Manufacture of Clinical Supply Requirements of such Licensed Product shall be coordinated with Manufacture of Commercial Supply Requirements of such Licensed Product. Formulated Bulk Product and/or Finished Product Manufactured by or on behalf of a Party for Commercial Supply Requirements, and for Clinical Supply Requirements that are Manufactured in coordination with the Commercial Supply Requirements, will be billed at the Manufacturing Cost described in Part II of Schedule 1 as a Commercial Supply Cost and Clinical Supply Cost, respectively. If a Party has commercial scale capacity available in anticipation of beginning to Manufacture Commercial Supply Requirements, the JMC shall decide if such Party shall Manufacture any Clinical Supply Requirements even before it begins to Manufacture Commercial Supply Requirements.

(c) Any Third Party manufacturer of Commercial Supply Requirements or Clinical Supply Requirements will be required to enter into a separate confidentiality agreement with Regeneron prior to the transfer of the manufacturing operations from Regeneron to such Third Party. All of Regeneron's costs and expenses associated with the transfer of the manufacturing operations and related Know-How to the Third Party manufacturer (or Sanofi, to the extent that Sanofi manufactures all or part of the Commercial Supply Requirements or Clinical Supply Requirements) will be billed as a Development Cost.

8.4 Supply Agreement. The Parties shall enter into one or more clinical supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements, which shall contain terms consistent with this Agreement. At least ********** of a Licensed Product, the Parties shall enter into separate commercial supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements and Commercial Supply Requirements after the First Commercial Sale, which shall contain terms consistent with this Agreement. Each supply agreement will include as an annex thereto a customary quality

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3377

Samsung Bioepis Exhibit 1017, pg. 3377

agreement containing terms and conditions regarding quality assurance and Good Practices and provide for terms for forecasting, ordering, delivery, payment and supply consistent with the terms of this Agreement.

8.5 Process Development and Manufacturing Plans. The Parties, through the JMC, will develop and update as necessary, for each Licensed Product, a Manufacturing Plan. The JMC shall be responsible for deciding on process and technology selection, on process improvements and all related process development activities which impact manufacturing. The JMC shall also be responsible for all decisions relating to Manufacturing Formulated Bulk Product for Clinical Supply Requirements of Licensed Products. Each Manufacturing Plan shall set forth the supply requirements of a Licensed Product over an ensuing period of at **********. The Manufacturing Plan will include arrangements for the Manufacture of back-up Formulated Bulk Product for Licensed Product requirements at a Party or a Third Party back-up Manufacturing facility. The Manufacturing Plan (including each annual update thereto) shall be prepared by the JMC and approved by the JSC at least two (2) months prior to the end of the then current Contract Year, except that the initial Manufacturing Plan covering at least initial expected Clinical Supply Requirements for a Licensed Product, to the extent not included in the Initial Development Plan, shall be approved by the JSC within the initial Global Development Plan. The Parties shall design Manufacturing Plans to ensure an adequate supply of Licensed Product and shall use Commercially Reasonable Efforts to perform their responsibilities in accordance with the approved Manufacturing Plans.

8.6 Manufacturing Shortfall. Each Party is required to provide prompt written notice to the other Party if it reasonably determines that it will not, despite its using Commercially Reasonable Efforts, be able to supply the agreed upon demand forecast for the Licensed Products set forth in the Manufacturing Plan. Upon such notification, the matter will be referred to the JMC and JSC to determine what, if any (and identify and establish, as quickly as possible, if applicable) alternative supply source of Licensed Product (including the other Party) should be utilized.

8.7 Manufacturing Compliance. Each Party will use diligent efforts to Manufacture the Formulated Bulk Product and Finished Product supplied under this Article VIII or, as applicable, to ensure that the same is Manufactured by Third Parties in conformity with Good Practices and applicable Laws. Each Party will timely notify and seek the approval of the other Party, which approval shall not be unreasonably withheld or delayed, for any Manufacturing changes for the Formulated Bulk Product or Finished Product that are reasonably likely to have an adverse impact on (a) the quality of the Licensed Products supplied under this Agreement or (b) the regulatory status of the Licensed Products in the Territory, including requirements to support or maintain any Approvals. Each Party shall have the right to conduct inspections and audits of the other Party's facilities involved in the Manufacture of Licensed Products in the Field pursuant to this Agreement at reasonable times and on reasonable prior notice on terms to be agreed upon by the Parties. Moreover, each Party will use diligent efforts to negotiate agreements that would allow the other Party to audit the facilities of Third Party contractors (including Sanofi, if applicable) involved in the Manufacture of Licensed Products for use in the Field under this Agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3378

Samsung Bioepis Exhibit 1017, pg. 3378

ARTICLE IX
PERIODIC REPORTS; PAYMENTS

9.1 Development Costs. Sanofi shall be responsible for paying one hundred percent (100%) of the total Development Costs for each Licensed Product incurred by or on behalf of Sanofi, Regeneron and their respective Affiliates, except that Shared Phase 3 Trial Costs will be shared eighty percent (80%) by Sanofi and twenty percent (20%) by Regeneron. **********.

9.2 Milestone Payments. In addition to the other payments contemplated herein, Sanofi shall be obligated to pay the non-refundable, non-creditable milestone payments listed in Schedule 3 to Regeneron upon the occurrence of the applicable milestone event. Sanofi shall have thirty (30) Business Days after the achievement of any such milestones to pay the corresponding amount to Regeneron, in each case, which shall not be reduced by any withholding or similar taxes.

9.3 Royalties. Any royalty amounts payable pursuant to Section 2.6(d) and 5.6 of this Agreement shall be paid to the applicable Party for the period of time, as determined on an Opt-Out Product-by-Opt-Out Product and country-by-country basis, commencing on the first commercial sale of such Opt-Out Product and ********** (the "Royalty Term"). During the Royalty Term, the paying Party shall deliver to the other Party with each royalty payment a report detailing in reasonable detail the information necessary to calculate the royalty payments due under this Section 9.3 for such calendar quarter, including the following information, specified on an Opt-Out Product-by-Opt-Out Product and country-by-country basis: (a) total gross invoiced amount from sales of each such Opt-Out Product by the paying Party, its Affiliates and sublicensees; (b) all relevant deductions from gross invoiced amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable.

9.4 Sharing of Profits from Licensed Products. Commencing on the Effective Date and continuing during the Term, the Parties shall share the U.S. Profit Split in the United States, and (ii) the Rest of World Profit Split in the Rest of World Countries, in each case, as described in Schedule 2.

9.5 Periodic Reports. Sanofi and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:

(a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Section 5.4;

(b) Within twenty (20) days following the end of each month, commencing with the month in which First Commercial Sale occurs, Sanofi shall deliver electronically to Regeneron a monthly detailed Net Sales report with monthly and year-to-date sales for each Licensed Product in the Field in the Territory by country in United States Dollars;

(c) Within forty-five (45) days following the end of each Quarter, commencing with the Quarter in which First Commercial Sale occurs, Sanofi shall

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3379

Samsung Bioepis Exhibit 1017, pg. 3379

deliver electronically to Regeneron a written report setting forth, on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each Licensed Product in local currency and in United States Dollars, (ii) Licensed Product quantities sold in the Field by dosage form and unit size and (iii) gross Licensed Product sales in the Field and an accounting of the deductions from gross sales permitted by the definition of Net Sales;

(d) Within forty-five (45) days following the end of each Quarter, each Party that has incurred any Other Shared Expenses or Shared Commercial Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses and/or Shared Commercial Expenses incurred by such Party in such Quarter on a country-by-country and Licensed Product-by-Licensed Product basis, including whether any such expenses are also included in the reports delivered pursuant to clause (e) below;

(e) Within forty-five (45) days after the end of each Quarter, commencing with the Quarter in which First Commercial Sale in a Reporting Country/Region occurs (or such earlier agreed upon calendar Quarter, if appropriate), Sanofi shall provide to Regeneron, in electronic form, for each Reporting Country/Region, and Regeneron shall provide to Sanofi, in electronic form, for each Co-Commercialization Country, a report summarizing in reasonable detail the marketing, detailing, selling and promotional activities undertaken by a Party (or its Affiliates) during the previous Quarter in such Reporting/Country Region and/or Co-Commercialization Country; and

(f) Within sixty (60) days following the end of each Quarter, Sanofi shall deliver electronically to Regeneron a Consolidated Payment Report in respect of such Quarter, combining the information reported by each Party pursuant to this Article IX and showing its calculations in accordance with Schedule 2 of the amount of any payments to be made by the Parties hereunder for such Quarterly period as contemplated by Section 9.5 (including, as applicable, showing the calculation of the U.S. Profit Split and Rest of World Profit Split) and, if applicable, providing for the netting of such payments.

All reports referred to in this Section 9.5 shall be in such form, format and level of detail as may be approved by the JFC. Unless otherwise agreed by the JCC, the financial data in the reports will include calculations in local currency and United States Dollars.

9.6 Funds Flow. The Parties shall make Quarterly True-Up payments as set forth in Schedule 2. If Sanofi is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report, it shall, subject to Section 9.12, make such payment to Regeneron within fifteen (15) days after its delivery to Regeneron of such Consolidated Payment Report. If Regeneron is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report, it shall, subject to Section 9.12, make such payment to Sanofi within fifteen (15) days after its receipt of such Consolidated Payment Report from Sanofi. Notwithstanding the foregoing, no later than fifty-five (55) days after the end of each Quarter, Sanofi shall pay Regeneron fifty percent (50%) of the amount of royalties or other amounts payable under any License (to the extent attributable to

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3380

Samsung Bioepis Exhibit 1017, pg. 3380

the Manufacture, Development and/or Commercialization of Licensed Products under the Plans for the Territory) to which Regeneron is a party on account of the Commercialization of Licensed Products in the Field in the Territory and provide such supporting documentation required by such License, as the case may be.

9.7 Invoices and Documentation. The JFC shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder.

9.8 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars using the average of the buying and selling exchange rates for conversion of the applicable foreign currency into United States Dollars, using the spot rates (the "Closing Mid-Point Rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties) from the last Business Day of the preceding month.

9.9 Late Payments. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. All late payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (Eastern Edition) effective for the date on which the payment was due, plus ********** (such sum being referred to as the "Default Interest Rate").

9.10 Taxes. Except as set forth in Section 9.2, any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall promptly furnish to the other Party proper evidence or other reasonable documentation of the taxes so paid. Each Party shall cooperate with the other and furnish to the other Party appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). Without limiting the foregoing, each Party agrees to make all lawful and reasonable efforts to minimize any such taxes, assessments and fees and will claim on the other Party's behalf the benefit of any available treaty on the avoidance of double taxation that applies to any payments hereunder to such other Party.

9.11 Adjustments to FTE Rates. Notwithstanding anything herein to the contrary, upon the request of either Party, the Parties shall meet to review the accuracy of an applicable FTE rate in any country (e.g., Sales Force FTE Rate, Medical Post-Approval FTE Rate, Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3381

Samsung Bioepis Exhibit 1017, pg. 3381

and materials in connection with an assessment of the applicable FTE rate and to determine in good faith whether to adjust the rate(s) in any country.

9.12 Resolution of Payment Disputes. In the event there is a dispute relating to any of the payment obligations or reports under this Article IX, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. In the event that no resolution is reached by the JFC, the matter shall be referred to the JSC in accordance with Section 3.11(a). Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder, provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

ARTICLE X
DISPUTE RESOLUTION

10.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement and to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article III ("Governance Disputes") shall be resolved pursuant to Article III and, to the extent such matters constitute Technical Development Matters, a dispute referred to in Section 14.2(b) or a Budget Dispute, Section 10.4, except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply. For the purposes of this Agreement, the term "Technical Development Matter" shall mean any dispute concerning a Party's refusal to approve a clinical trial proposed pursuant to Section 2.6(b).

10.3 Legal Disputes. The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the Effective Date by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute within five (5) Business Days of receipt by a Party of notice of such Legal Dispute, either Party may submit the Legal Dispute to the Executive Officers for resolution. In the event the Executive Officers are unable to resolve any such Legal Dispute within the time period set forth in Section 3.11(b), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1 and Section 20.15.

10.4 Expert Panel.

(a) In the event of a dispute between the Parties concerning a Technical Development Matter, any Budget Dispute or a dispute referred to in Section

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3382

Samsung Bioepis Exhibit 1017, pg. 3382

14.2(b) that cannot be resolved by the Executive Officers pursuant to Section 3.11(b) (other than a Legal Dispute), either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts ("Expert Panel") in accordance with this Section 10.4 (for the avoidance of doubt, it is understood that, subject to Section 10.4(e), in the case of a Budget Dispute first submitted to the Expert Panel, the specific issue shall be limited to the overall commercial reasonableness of the Disputed Budget). Such notice shall contain a statement of the issue forming the basis of the dispute, the position of the moving Party as to the proper resolution of that issue and the basis for such position. Within fifteen (15) days after receipt of such notice, the responding Party shall submit to the moving Party a statement of its conception of the specific issue in question, its position as to the proper resolution of that issue and the basis for such position.

(b) Within fifteen (15) days of the responding Party's response, each Party shall appoint to the Expert Panel an individual who (i) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue (or, in the case of a dispute regarding an audit as referred to in Section 14.2(b), expertise in accounting and auditing with respect to the development and commercialization of pharmaceutical products), (ii) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past five (5) years and (iii) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (i) through (iii) above, disclosing any potential conflict or bias and certifying that, as a member of the Expert Panel, such individual is able to render an independent decision.

(c) Within fifteen (15) days of the appointment of the second (2nd) expert, the two (2) appointed experts shall agree on an additional expert who meets the same criteria as described above, and shall appoint such expert as chair of the Expert Panel. If the Party-appointed experts fail to timely agree on a third (3rd) expert, then upon the written request of either Party, each Party-appointed expert shall, within ten (10) days of such request, nominate one expert candidate and the CPR Institute for Dispute Resolution shall, within ten (10) days of receiving the names of the Parties' respective nominees, select one of those experts to serve as the chair of the Expert Panel. Each expert shall agree, prior to his or her appointment, to render a decision as soon as practicable after the appointment of the full Expert Panel.

(d) Within seven (7) days of the appointment of the third (3rd) expert, the Expert Panel shall hold a preliminary meeting or teleconference with the Parties or their representatives and shall designate a time and place for a hearing of the Parties on the dispute and the procedures to be utilized at the hearing. The Parties may agree in writing to waive the hearing and have the Expert Panel reach a decision on the basis of written submissions alone. The Expert Panel may order the Parties to produce any documents or

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3383

Samsung Bioepis Exhibit 1017, pg. 3383

documents or information which are relevant to the dispute. All such documents or information shall be provided to the other Party and the Expert Panel as expeditiously as possible but no later than one (1) week prior to the hearing (if any), along with the names of all witnesses who will testify at the hearing and a brief summary of their testimony. The hearing shall be held in New York, NY, unless otherwise agreed by the Parties, and shall take place as soon as possible but no more than forty-five (45) days after the appointment of the third expert, unless the Parties otherwise agree in writing or the Expert Panel agrees to extend such time period for good cause shown. The hearing shall last no more than one (1) day, unless otherwise agreed by the Parties or the Expert Panel agrees to extend such time period for good cause shown. After the conclusion of all testimony (or if no hearing is held after all submissions have been received from the Parties), at a time designated by the Expert Panel no later than seven (7) days after the close of the hearing or the receipt of all submissions, each Party shall simultaneously submit to the Expert Panel and exchange with the other Party its final proposed resolution (which, in the case of a Budget Dispute first submitted to the Expert Panel shall be a Party's proposed resolution that the Disputed Budget either is or is not overall commercially reasonable).

(e) In rendering the final decision with respect to a Budget Dispute first submitted to the Expert Panel, the Expert Panel shall be limited to determining the overall commercial reasonableness of the Disputed Budget. If the Expert Panel determines that such Disputed Budget is overall commercially reasonable, then such Budget Dispute shall be deemed finally resolved and such resolution shall be binding on the Parties. However, if the Expert Panel determines that such Disputed Budget is not overall commercially reasonable, then the Expert Panel shall, within fifteen (15) days after such determination, render a final decision as to what modifications could be made to such Disputed Budget in order for it to be overall commercially reasonable (a "Budget Modification Decision"). In connection with reaching a Budget Modification Decision, the Expert Panel shall order the Parties to produce any documents or other information which are relevant to such final decision, and the Parties shall submit such documents or other information, together with their respective proposed resolutions which shall consist of their respective proposed modifications to the Disputed Budget in order for it to be overall commercially reasonable, at least seven days prior to the date a Budget Modification Decision is required to be rendered as provided above. In rendering the final decision (which, for other than a Budget Modification Decision, shall be rendered no later than fifteen (15) days after receipt by the Expert Panel of the Parties' respective proposed resolutions, and for a Budget Modification Decision, shall be rendered no later than seven days after receipt by the Expert Panel of the Parties' respective proposed resolutions), the Expert Panel shall be limited to choosing a resolution proposed by a Party without modification; provided, however, that in no event shall the Expert Panel render a decision that is inconsistent with the Collaboration Purpose and the Parties' intentions as set forth in this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.

(f) The decision of the Expert Panel shall be final and binding on the Parties and may be entered and enforced in any court having jurisdiction. Each Party

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3384

Samsung Bioepis Exhibit 1017, pg. 3384

shall bear the cost of its appointee to the Expert Panel and the Parties shall share equally the costs of the third expert.

10.5 No Waiver. Nothing in this Article X or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

ARTICLE XI
TRADEMARKS AND CORPORATE LOGOS

11.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

11.2 Selection of Product Trademarks. For each Licensed Product, the JCC shall select one Product Trademark for use in the Field throughout the Territory, unless such Product Trademark is prohibited by law in any country in the Territory or the JCC determines that a different Product Trademark should be used in particular countries or Regions to maximize the commercial potential of such Licensed Product. Once a Product Trademark has been selected by the JCC, the Parties shall enter into an agreement or, in the alternative, shall amend this Agreement as the Parties may agree, in order to address the Parties' respective rights and obligations with respect to such Product Trademark. Each Licensed Product in the Field shall be promoted and sold in the Territory under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.

11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, and subject to Sections 11.4 and 11.5, Sanofi (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s), together with all associated domain names and all goodwill related thereto in all countries in the Territory.

11.4 Prosecution and Maintenance of Product Trademark(s). Sanofi will use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark(s) in all countries in the Territory. Notwithstanding the foregoing, in the event Sanofi elects not to prosecute or maintain any Product Trademark(s) in any country in the Territory, Sanofi shall provide reasonable prior written notice to Regeneron of its intention not to prosecute or maintain any such Product Trademark in such country in the Territory, and Regeneron shall have the right to do so on behalf of Sanofi for use with Licensed Products, subject to consultation and cooperation with Sanofi. All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of Product Trademarks as provided in this Section 11.4 shall be shared by the Parties as part of Shared Commercial Expenses.

11.5 License to the Product Trademark(s). Sanofi hereby grants to Regeneron a co-exclusive license (non-exclusive only with respect to Regeneron) to use the Product Trademark(s) for the Licensed Products solely for the purposes of Regeneron's Development, Manufacturing, and, if applicable, Co-Promotion of Licensed Products, or other Regeneron Commercialization activities with respect to Licensed Products if agreed to by Sanofi or set forth

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3385

Samsung Bioepis Exhibit 1017, pg. 3385

in any Plans, subject to the terms and conditions of this Agreement. Consistent with Section 4.4 of this Agreement, neither Party shall license (or in the case of Regeneron, sublicense) rights to use, or otherwise transfer ownership of the Product Trademark(s) without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Sanofi shall only utilize the Product Trademark(s) on approved Promotional Materials, on the Licensed Products as needed and on or other approved product-related materials for the Licensed Products in the Field in the Territory for the purposes contemplated herein, and all use by Sanofi or its Affiliates or Sublicensees of the Product Trademark(s) shall be in accordance with (a) rules established by the JCC and (b) quality standards established by the JCC which are reasonably necessary in order to preserve the validity and enforceability of the Product Trademark(s). Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the Product Trademark(s) in relation to a product that is a Licensed Product, or take any other action which damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or a recordable version thereof, referred to above in this Section 11.5.

11.6 Use of Corporate Names. Sanofi (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include Regeneron's name with equal prominence on materials related to each Licensed Product in the Field (including, without limitation, package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with such Licensed Product), unless to do so would be prohibited under applicable Laws; provided, however, in the case of multi-product materials that refer to a Licensed Product in the Field as well as other pharmaceutical products, the prominence of Regeneron's name shall be commensurate with the relative prominence of the Licensed Product in such materials. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with the applicable Licensed Product in the Field in the Territory during the Term and thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging and samples, only for the time period and solely to the extent necessary to exhaust the existing inventory of Licensed Product (including packaging materials for such Licensed Product) and Promotional Materials containing such name or logo. During the Term, each Party shall submit samples of each such package inserts, packaging, trade packaging, etc. to such other Party for its prior approval, which approval shall not be unreasonably withheld or delayed, at least thirty (30) days before dissemination of such materials. Failure of the receiving Party to object within such thirty (30) day period shall constitute approval of the submitting Party's package inserts, packaging, trade packaging, etc.

ARTICLE XII
NEWLY CREATED INVENTIONS AND KNOW-HOW

12.1 Ownership of Newly Created Intellectual Property.

(a) Subject to Section 12.1(e), each Party (and each Party's respective Affiliates) shall exclusively own all intellectual property (including, without limitation,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3386

Samsung Bioepis Exhibit 1017, pg. 3386

Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created in connection with the Collaboration solely by such Party, its Affiliates, employees, agents and consultants ("Sole Inventions"). Sole Inventions made solely by Sanofi, its Affiliates, employees, agents and consultants are referred to herein as "Sanofi Sole Inventions". Sole Inventions made solely by Regeneron, its Affiliates, employees, agents and consultants are referred to herein as "Regeneron Sole Inventions". The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder. Any remuneration payable under applicable law to an inventor and costs associated with determining such remuneration shall be treated as Other Shared Expenses.

(b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Collaboration during the Term that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Sanofi or its Affiliate (or for which ownership vests in Sanofi or its Affiliate by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron or its Affiliate (or for which ownership vests in Regeneron or its Affiliate by operation of Law), on the other hand, on the basis of each Party (or its Affiliate) having an undivided interest in the whole ("Joint Inventions").

(c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under the Collaboration during the Term vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) Subject to the other terms and conditions of this Agreement (other than Section 12.1(a)), to the extent permitted under any relevant Third Party agreement, each Party agrees that all Know-How, other than Excluded Know-How Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3387

Samsung Bioepis Exhibit 1017, pg. 3387

Effective Date directly in connection with the performance of the research and clinical activities approved by the JDC, in each case, as included in the Global Development Plans shall be Joint Inventions. Each Party agrees to execute all necessary documentation to reflect the foregoing. As used above, the term "Excluded Know-How Rights" shall mean any Know-How claiming or covering composition (including any formulation) of a Licensed Product, including, for the avoidance of doubt, any manufacturing and/or cell line related intellectual property. For further clarity, nothing in this Section 12.1(e) shall be construed to grant either Party any rights to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities approved by the JDC and/or the clinical development activities approved by the JDC, in each case, as included in Global Development Plans.

(f) The Parties hereby agree that each Party's use of the Joint Inventions is governed by the terms and conditions of this Agreement shall be governed as follows: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as may be expressly set forth in Article IV, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 12.1(e) and (iii) nothing in this Article XII shall relieve a Party or its Affiliates of their obligations under Article XVI with respect to confidential Party Information provided by the other Party or such other Party's Affiliates. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. Neither Party hereto shall have the obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Collaboration. The provisions governing Joint Inventions set forth in this Section 12.1(e) shall survive the expiration or termination of this Agreement.

12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights in the Territory. Regeneron shall undertake such activities using outside counsel reasonably acceptable to Sanofi except that all provisionals, the priority application based thereon and the corresponding PCT may be prepared and filed by Regeneron's in-house counsel. Regeneron shall confer with and keep Sanofi reasonably informed regarding the status of such activities. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of Regeneron Patent Rights: (i) Regeneron shall provide to Sanofi for review and comment a substantially completed draft of any

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3388

Samsung Bioepis Exhibit 1017, pg. 3388

priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Regeneron and incorporate any reasonable comment from Sanofi within such thirty (30) day period unless Regeneron reasonably believes that such comments will adversely affect the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Regeneron shall provide Sanofi promptly with copies of all material communications received from or filed in patent offices in the Territory with respect to such filings; (iii) Regeneron shall consult with Sanofi promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications, provided, however, applications shall be filed in at least ********** (the "Patent Jurisdictions") unless otherwise agreed in writing; and (iv) Regeneron shall consult with Sanofi a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Regeneron desires to abandon any Patent included in the Regeneron Patent Rights in the Territory, Regeneron shall provide reasonable prior written notice to Sanofi of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Regeneron Patent with the applicable patent office) and Sanofi shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof, in Regeneron's name or Sanofi's name at Sanofi's sole discretion, unless, with respect to any such Patent Applications that are unpublished, Regeneron notifies Sanofi that Regeneron would prefer to maintain the subject matter of such Patent Application as a trade secret and Sanofi agrees in writing.

(b) Sanofi shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Sanofi Patent Rights in the Territory and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Sanofi shall have the following obligations with respect to the filing, prosecution and maintenance of Sanofi Patent Rights: (i) Sanofi shall provide to Regeneron for review and comment a copy of a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Sanofi and incorporate any reasonable comment from Regeneron unless Sanofi reasonably believes that such comments will adversely affect the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Sanofi shall provide Regeneron promptly with copies of all material communications received from or filed in patent offices with respect to such filings; (iii) Sanofi shall consult with Regeneron promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications, provided, however, applications shall be filed in at least the Patent Jurisdictions unless otherwise agreed in writing; and (iv) Sanofi shall

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3389

Samsung Bioepis Exhibit 1017, pg. 3389

consult with Regeneron a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Sanofi desires to abandon any Patent included in the Sanofi Patent Rights in the Territory, Sanofi shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Sanofi Patent with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Sanofi's name, unless, with respect to any such Patent Applications that are unpublished, Sanofi notifies Regeneron that Sanofi would prefer to maintain the subject matter of such Patent Application as a trade secret and Regeneron agrees in writing.

(c) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners through outside counsel reasonably acceptable to the non-Controlling Party, except that the Controlling Party may prepare and file all provisional applications, priority applications based thereon and the corresponding PCTs using in-house counsel. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents under any such Joint Patent Rights: (i) the Controlling Party shall provide the non-Controlling Party with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by the Controlling Party and incorporate any reasonable comment provided by the non-Controlling Party within such thirty (30) day period (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent Application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications provided, however, applications shall be filed in at least the Patent Jurisdictions unless otherwise agreed in writing; (iv) the Controlling Party shall provide the non-Controlling Party promptly with copies of all material communications received from or filed in patent offices with respect to such filings and the Parties use all reasonable efforts to reach agreement in a timely manner with respect to all material responses and amendments; and (v) the Controlling Party shall provide the non-Controlling Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office (including but not limited to substantially narrowing or canceling any claim without reserving the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3390

Samsung Bioepis Exhibit 1017, pg. 3390

right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Controlling Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the non-Controlling Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof. Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Patent or Patent Application relating to any Joint Patent Rights on thirty (30) days' prior written notice to the other Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the non-Controlling Party a free-of-charge option to assume the prosecution or maintenance thereof.

(d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patents and Patent Applications pursuant to this Section 12.2, including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The JCC, with the approval of the JSC, will determine which of the Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights for which to seek an extension of term and the applicable Party will file for said patent term extension.

(e) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights in the Territory for use in the Field, and any extensions thereof, shall be treated as Other Shared Expenses.

12.3 Interference, Opposition and Reissue.

(a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition or reexamination relating to Regeneron Patent Rights, Sanofi Patent Rights or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. The Parties will reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3391

Samsung Bioepis Exhibit 1017, pg. 3391

provided that if such agreement cannot be reached promptly, such decisions will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron and (iii) with respect to Joint Patent Rights, jointly by the Parties.

(b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Regeneron Patent Rights, Sanofi Patent Rights and/or Joint Patent Rights in the Territory for use in the Field shall be treated as Other Shared Expenses.

ARTICLE XIII
INTELLECTUAL PROPERTY LITIGATION AND LICENSES

13.1 Third Party Infringement Suits.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual, potential or suspected infringement of a Sanofi Patent Right, a Regeneron Patent Right, a Joint Patent Right, Product Trademark or any other intellectual property right jointly owned or licensed under this Agreement, by a Third Party's activities in the Field in the Territory, the Party that became aware of the infringement shall promptly notify the other Party in writing of this claim or assertion and shall provide such other Party with all available evidence supporting such known, potential or suspected infringement or unauthorized use. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the JSC to meet and consider the appropriate course of action with respect to such infringement. The Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution and/or settlement of any such claim.

(b) With respect to any such actual, suspected or potential infringement by virtue of a generic or potential generic competitor's activities in the Field in the Territory, including but not limited to, any ANDA filing, Paragraph IV Certification (or the equivalent for biologics) or other actual or potential infringement by a generic or potential generic competitor anywhere in the Territory, the Parties will consult and cooperate fully to determine a course of action. Final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made by Sanofi with active assistance from and in consultation with Regeneron. Regeneron will provide reasonable assistance to Sanofi in prosecuting any suit, and if required by Law, will join in the suit. Although Sanofi has the right to select counsel of its own choice, it shall first consult with Regeneron and consider in good faith the recommendations of Regeneron. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs, including attorneys' fees, relating to such legal proceedings and then shared equally by the Parties or according to the U.S. Profit Split and Rest of World Profit Split if and as applicable.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3392

Samsung Bioepis Exhibit 1017, pg. 3392

(c) With respect to all other such actual, potential or suspected infringement by virtue of a Third Party's activities in the Field in the Territory, the Parties will consult and cooperate fully in an effort to determine a mutually agreeable course of action, provided if such agreement cannot be reached promptly, final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties. Any disagreement between the Parties concerning the enforcement of Joint Patent Rights shall be referred to the Executive Officers for resolution. The Party initiating the litigations shall be referred to as the "Lead Litigation Party." The non-Lead Litigation Party will provide reasonable assistance to the Lead Litigation Party in prosecuting any suit, and if required by Law, will join in the suit. Although the Lead Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs, including attorneys' fees, relating to such legal proceedings and then shared equally by the Parties.

(d) All Out-of-Pocket Costs incurred in connection with any litigation under Section 13.1(b) or (c) related to activities in the Field in the Territory shall be treated as Other Shared Expenses.

(e) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 13.1 that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent. Furthermore, no Party shall enter into any Third Party intellectual property license requiring the payment of royalties or other amounts based on the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory under this Agreement without the other Party's prior written consent.

13.2 Patent Marking. Each Party shall comply with the patent marking statutes in each country in which a Licensed Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates and/or Sublicensees.

13.3 Third Party Infringement Claims; New Licenses.

(a) If either Party or its Affiliates shall learn of an allegation that the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this allegation. As soon as reasonably practicable after the receipt of such notice and at all times thereafter, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement. In any such instance, each Party shall have the right to defend any action naming it using its own

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3393

Samsung Bioepis Exhibit 1017, pg. 3393

counsel; however, the Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense and/or settlement of any such claim. The rights and obligations in this Section 13.3 shall apply even if only one Party defends any claimed infringement action commenced by a Third Party in the Territory claiming that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes or otherwise violates any intellectual property rights of any Third Party.

(b) Except as otherwise set forth in this Agreement, all Out-of-Pocket Costs (except for the expenses of the non-controlling Party's counsel, if only one Party defends a claim) incurred in connection with any litigation referred to in this Section 13.3 shall be treated as Other Shared Expenses.

(c) **********.

(d) License fees, royalties and other payments under Licenses to the extent attributable to, and based on, the discovery, Development and Manufacture of Commercial Supply Requirements or the Commercialization of Licensed Products in the Field in the Territory shall be treated as Other Shared Expenses.

(e) **********.

ARTICLE XIV
BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

14.1 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with GAAP or IAS/IFRS) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

14.2 Audits and Adjustments.

(a) Each Party shall have the right (at its own cost), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3394

Samsung Bioepis Exhibit 1017, pg. 3394

any Contract Year, to have the books and records of the other Party and its Affiliates to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to dispute resolution in accordance with Article X. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than seven and one-half percent (7.5%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article XVI.

(c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then unless the result of the audit is to be contested pursuant to Section 14.2(b) above, the Party owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section.

14.3 GAAP/IAS/IFRS. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with, at a Party's election, GAAP or IAS/IFRS.

ARTICLE XV
REPRESENTATIONS, WARRANTIES AND COVENANTS

15.1 Due Organization, Valid Existence and Due Authorization; Financial Capability. Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate (or, in the case of Sanofi Amerique, partnership) power and authority and has taken all corporate (or, in the case of Sanofi Amerique, partnership) action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement by which it is bound or any requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3395

Samsung Bioepis Exhibit 1017, pg. 3395

accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under Article IV hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Each Party hereby represents and warrants to the other Party that such Party has, and will continue to have, sufficient liquid assets to promptly and timely pay and perform all of the payments and obligations required by such Party or its Affiliates to be paid and performed by them hereunder.

15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any Governmental Authority or arbitrator that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

15.3 Additional Regeneron Representations, Warranties and Covenants. Regeneron additionally represents and warrants to Sanofi that, as of the Effective Date:

(a) Regeneron owns all right, title and interest in and to all Regeneron Patent Rights in existence as of the Effective Date;

(b) Regeneron has the right and authority to grant the rights granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;

(c) there is no pending litigation that alleges that any of Regeneron's activities relating to the Regeneron Intellectual Property have violated, or would violate, the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation);

(d) to Regeneron's knowledge, no litigation has been otherwise threatened which alleges that any of its activities relating to the Regeneron Intellectual Property have violated or would violate, any intellectual property rights of any Third Party;

(e) the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Effective Date has not constituted or involved the misappropriation of trade secrets or other rights of any Person;

(f) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Effective Date are not invalid or unenforceable, in whole or part;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3396

Samsung Bioepis Exhibit 1017, pg. 3396

(g) Regeneron has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings; and

(h) Regeneron has enforceable written agreements with all of its employees and contractors who may participate in the conduct of the Collaboration or receive Confidential Information hereunder assigning to Regeneron ownership of all intellectual property rights created in the course of their employment or provision of services, as applicable.

15.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT IN THE FIELD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15.5 Mutual Covenants. Each Party hereby covenants to the other Party as of the Effective Date as follows: (a) it will not during the Term grant any right or license to any Third Party in the Territory which would be inconsistent with or in conflict with or in derogation of the rights granted to the other Party under this Agreement, and will not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement; (b) neither Party will use the Patent Rights or Know-How of the other Party outside the scope of the licenses and rights granted to it under this Agreement; and (c) in the course of the Development or Commercialization of a Licensed Product in the Field under this Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

ARTICLE XVI
CONFIDENTIALITY

16.1 Confidential Information.

(a) Each of Sanofi and Regeneron acknowledges (subject to the further provisions of this Article XVI and the provisions of Article XIX) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement (or, in the case of Sanofi, Party Information provided to it under the Confidentiality Agreements is confidential and proprietary to such other Party. Furthermore, each of Sanofi and Regeneron acknowledges (subject to the further provisions of this Article XVI) that all New

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3397

Samsung Bioepis Exhibit 1017, pg. 3397

Information is confidential and proprietary to both Parties. Subject to the further provisions of this Article XVI, each of Sanofi and Regeneron agrees to (i) maintain such Party Information of the other Party (or its Affiliates) and all New Information in confidence during the Term and for a period of ten (10) years thereafter and (ii) use such Party Information of the other Party (or its Affiliate) and New Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such Party Information of the other Party (or its Affiliate) or New Information to any Third Party except (A) to its employees, agents, consultants or any other Person under its authorization; provided such employees, agents, consultants or Persons are subject in writing to substantially the same confidentiality obligations as the Parties, (B) as approved by both Parties hereunder or (C) as set forth elsewhere in this Agreement.

(b) Notwithstanding anything provided above, the restrictions provided in this Article XVI shall not apply to information that was or is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information; (iv) similar in nature to the purported Party Information or New Information but has been independently created, as evidenced by written or electronic documentation, without any aid, application or use of the Party Information or New Information; (v) necessary to file, prosecute or defend Patents and Patent Applications for which the Party has the right to assume filing, prosecution, defense or maintenance pursuant to this Agreement; or (vi) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded), or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable, and provided, further, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information which is required by Governmental Authority, applicable Law (including the rules or regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded) or court order to be disclosed. Moreover, either Party may use Party Information and New Information to enforce the terms of this Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3398

Samsung Bioepis Exhibit 1017, pg. 3398

(c) Notwithstanding anything provided above or elsewhere in this Agreement, Regeneron and its Affiliates shall have the right to use and disclose any New Information directly related to any Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law.

(d) Notwithstanding anything provided above or elsewhere in this Agreement, Sanofi and its Affiliates shall have the right to use and disclose any New Information directly related to any Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law.

16.2 Injunctive Relief. The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

16.3 Publication of New Information. During the Term, if either Sanofi or Regeneron (the "Publishing Party") desires to disclose any New Information in scientific journals, publications or scientific presentations, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it or the Licensed Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material adverse effect) to which the Publishing Party shall give due consideration. Disputes concerning publication shall be resolved by the JDC (other than Legal Disputes).

16.4 Disclosures Concerning this Agreement. The Parties will mutually agree upon the contents of their respective press releases with respect to the execution of this Agreement and any Ancillary Agreement which shall be issued simultaneously by both Parties on the Effective Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement, any Ancillary Agreement or any actions or activities contemplated hereunder or thereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3399

Samsung Bioepis Exhibit 1017, pg. 3399

cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement, any Ancillary Agreement or any actions or activities contemplated hereunder or thereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding the Collaboration. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article XVI without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. The Parties, through the Committees, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the Licensed Products in the Field. Sanofi acknowledges that Regeneron as a publicly traded company may be legally obligated to make timely disclosures of material events relating to Licensed Products. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement and each Ancillary Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE XVII
INDEMNITY

17.1 Indemnity and Insurance.

(a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees, licensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Sanofi, its Affiliates or their respective directors, officers, employees, agents or Sublicensees, including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3400

Samsung Bioepis Exhibit 1017, pg. 3400

faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee; or

(ii) material breach by Sanofi of the terms of, or the inaccuracy when made of any representation or warranty made by it in, this Agreement.

(b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and their respective officers, directors, employees, Sublicensees and agents ("Sanofi Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Sanofi Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Regeneron, its Affiliates or their respective directors, officers, employees, licensees or agents including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions or violations of Law committed by Sanofi or any other Sanofi Indemnitee; or

(ii) material breach by Regeneron of the terms of, or the inaccuracy when made of any representation or warranty made by it in, this Agreement.

(c) In the event of any Third Party claim alleging that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes a Patent Right of a Third Party for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other Party for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.

(d) In the event of any Third Party product liability claim alleging that the Development or Commercialization of any Licensed Product in the Field causes damages for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.

(e) Each of Regeneron and Sanofi will use Commercially Reasonable Efforts to procure and maintain during the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by applicable Law in countries where the project is conducted, product liability insurance in an amount not less than ********** in the annual aggregate. Such insurance shall insure against liability on the part of Regeneron and Sanofi and any of its Affiliates, due to injury, disability or death of any person or persons, or property damage arising from services performed under this Agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3401

Samsung Bioepis Exhibit 1017, pg. 3401

(f) Notwithstanding anything to the contrary in this Section 17.1, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Sanofi Indemnitees, as the case may be) from Third Party claims resulting from, and to the extent allocable to, the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Third Parties contracted to Manufacture any part of the Clinical Supply Requirements or Commercial Supply Requirements pursuant to Article VIII; provided, however, that nothing in this Section 17.1(f) limits either Party's indemnification obligations to the extent any Third Party claims arise from the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed directly by the Party that is responsible for contracting with such Third Party Manufacturer(s) pursuant to Article VIII.

17.2 Indemnity Procedure. The Party entitled to indemnification under this Article XVII (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder. For the avoidance of doubt, the indemnification procedures in this Section 17.2 shall not apply to claims for which each Party indemnifies the other Party for fifty percent (50%) of all Damages, under the terms of Section 17.1(c).

(a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) such compromise or settlement does not (A) include any admission of legal wrongdoing by the Indemnified Party, (B) require any payment by the Indemnified Party that is not indemnified hereunder or (C) result in the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed); provided that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3402

Samsung Bioepis Exhibit 1017, pg. 3402

litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

(b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party.

(c) The amount of any Damages for which indemnification is provided under this Article XVII will be reduced by the insurance proceeds received, and any other amount recovered if any, by the Indemnified Party in respect of any such Damages.

(d) If an Indemnified Party receives an indemnification payment pursuant to this Article XVII and subsequently receives insurance proceeds from its insurer with respect to the Damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article XVII and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article XVII.

ARTICLE XVIII
FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

ARTICLE XIX
TERM AND TERMINATION

19.1 Term/Expiration of Term.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3403

Samsung Bioepis Exhibit 1017, pg. 3403

(a) The "Term" of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated in its entirety in accordance with this Article XIX, shall expire upon the later to occur of (i) the expiration of the Discovery Program, and (ii) such time as neither Party, nor either Party's Affiliates or Sublicensees, is Developing or Commercializing any Licensed Product in the Field in the Territory under this Agreement and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent.

(b) Upon expiration of the Term pursuant to Section 19.1(a) above, except as set forth in this Agreement, all licenses and rights with respect to Licensed Products shall automatically terminate and revert to the granting Party.

19.2 Termination Without Cause.

(a) By Sanofi. (i) Sanofi may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the Discovery Program in accordance with the terms of the Discovery Agreement, or may terminate this Agreement in the entire Territory for a particular Licensed Product or particular Licensed Products in the Field, in any such case on twelve (12) months' prior written notice to Regeneron. Except as otherwise provided below in this Section 19.2(a), in the event of such termination by Sanofi of this Agreement in its entirety or with respect to one or more Licensed Product(s) pursuant to this Section 19.2, this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the "Sanofi Termination Notice Period") and the terms of Schedule 4 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(a) or Schedule 4, during the Sanofi Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products (including the Opt-Out Products(s)) in the Field in accordance with Plans. During the Sanofi Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Sanofi hereunder and in any event upon the expiration of the Sanofi Termination Notice Period, whether or not any such notice is given by Regeneron, (i) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Opt-Out Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Sanofi Termination Notice Period), (ii) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Opt-Out Product(s) shall terminate, and (iii) Sanofi will promptly take the actions required by Schedule 4 and Regeneron will reasonably cooperate with Sanofi (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron's (or its nominee's) expeditious assumption during the Sanofi Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Opt-Out Product(s) in the Field in the Territory. In addition, during the Sanofi Termination Notice Period, neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3404

Samsung Bioepis Exhibit 1017, pg. 3404

change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Sanofi Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

(ii) In addition to Sanofi's termination rights set forth in Section 19.2(a)(i), from and after the twelfth (12th) anniversary of the First Commercial Sale of a Licensed Product in a country, Sanofi may, upon twenty-four (24) months' prior written notice to Regeneron, terminate this Agreement with respect to such Licensed Product in such country. If Sanofi exercises such right, the provisions of Section 19.2(a)(i) (except that the Sanofi Termination Notice Period referred to therein shall be twenty-four (24) months rather than twelve (12) months), and Sections 19.7(a) and 19.8 shall apply with respect to such Terminated Licensed Product in such country.

(b) By Regeneron. Regeneron may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the Discovery Program in accordance with its terms, or may terminate this Agreement in the entire Territory for a particular Licensed Product or particular Licensed Products in the Field, in any such case, on twelve (12) months' prior written notice to Sanofi. Except as otherwise provided below in this Section 19.2(b), in the event of such termination by Regeneron of this Agreement in its entirety or with respect to one or more Licensed Product(s) pursuant to this Section 19.2(b), this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the "Regeneron Termination Notice Period") and the terms of Schedule 5 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(b) or Schedule 5, during the Regeneron Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products (including the Opt-Out Products(s)) in the Field in accordance with Plans. During the Regeneron Termination Notice Period, to the extent set forth or requested in one or more written notices from Sanofi to Regeneron hereunder and in any event upon the expiration of the Regeneron Termination Notice Period, whether or not any such notice is given by Sanofi, (i) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Opt-Out Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Regeneron Termination Notice Period), (ii) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Opt-Out Products(s) shall terminate, and (iii) Regeneron will promptly take the actions required by Schedule 5 and Sanofi will reasonably cooperate with Regeneron (for avoidance of doubt, such cooperation shall not require Sanofi to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Sanofi) to facilitate Sanofi's (or its nominee's) expeditious assumption during the Regeneron Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Opt-Out Product(s) in the Field in the Territory. In addition, during the Regeneron Termination

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3405

Samsung Bioepis Exhibit 1017, pg. 3405

Notice Period, neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Regeneron Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety or for a particular Licensed Product or particular Licensed Products in the Field in the entire Territory, upon written notice to the other Party, if such other Party commits a material breach of its obligations under this Agreement with respect to such Licensed Product(s) as to which such notice of termination is given (or all Licensed Products if such notice of termination is with respect to this Agreement is in its entirety). Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days so long as the breaching party is using Commercially Reasonable Efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use Commercially Reasonable Efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be thirty (30) days (and the immediately preceding parenthetical clause in the immediately preceding sentence shall not apply). For purposes of this Section 19.3, the term "material breach" shall mean an intentional, continuing (and uncured within the time period described above) material breach by a Party, as determined by a court of competent jurisdiction.

19.4 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety, by and effective immediately, upon written notice to the other Party, if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, (b) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within ninety (90) days after the filing thereof or (c) if the other Party shall make a general assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties agree

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3406

Samsung Bioepis Exhibit 1017, pg. 3406

that all intellectual property rights licensed hereunder, including, without limitation, any patents or patent applications in any country of a party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

19.5 Termination for Breach of Standstill or Lock-Up. Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have breached their obligations under any of Sections 3, 4 or 5 of the Investor Agreement (to the extent such sections of the Investor Agreement is then in effect). Furthermore, Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have (a) breached their obligations under Section 20.16 of the Aventis Collaboration Agreement, to the extent that such Section 20.16 remains in effect after the Effective Date, or (b) breached its obligations under Section 5.3 of the Aventis Stock Purchase Agreement, to the extent that such Section 5.3 remains in effect after the Effective Date. Any such breach of the Investor Agreement, the Aventis Stock Purchase Agreement or the Aventis Collaboration Agreement, as the case may be, shall be treated as a breach of this Agreement. Notwithstanding the foregoing and for the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of (i) a de minimus breach of Section 3.1(a) of the Investor Agreement (to the extent such Section 3.1(a) is in effect after the Effective Date) or of Section 20.16(a) of the Aventis Collaboration Agreement (to the extent such Section 20.16(a) remains in effect after the Effective Date) or (ii) an inadvertent breach of Section 3.1(g) of the Investor Agreement (to the extent such Section 3.1(g) is in effect after the Effective Date) or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement (to the extent such Section 20.16(g) remains in effect after the Effective Date), arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of such Section 20.16 or of paragraphs (a) through (e) of Section 3.1 of the Investor Agreement, as applicable.

19.6 Termination of Discovery Agreement.

(a) By Regeneron. Regeneron may terminate this Agreement in its entirety, effective upon written notice to Sanofi, if the Discovery Agreement has been terminated by Regeneron pursuant to Section 12.2, 12.3 or 12.5 thereof.

(b) By Sanofi. Sanofi may terminate this Agreement in its entirety effective upon written notice to Regeneron, if the Discovery Agreement has been terminated by Sanofi pursuant to Section 12.2 or 12.3 thereof.

(c) Automatic. This Agreement shall automatically terminate in its entirety if, at the time the Discovery Agreement terminates for any reason pursuant to Article 12 thereof, Sanofi has not exercised its Opt-In Right pursuant to Section 5.3 of the Discovery Agreement with respect to any Product Candidate.

19.7 Effect of Termination.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3407

Samsung Bioepis Exhibit 1017, pg. 3407

(a) Except as provided in Section 19.2(b), and in Section 19.7(b) below, upon termination of this Agreement with respect to all Licensed Products in the Field, or for a particular Licensed Product or particular Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the provisions of Schedule 4 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated Licensed Product(s), and except to the extent required by Sanofi to fulfill its obligations pursuant to Schedule 4, (i) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate, and revert to Regeneron, (ii) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate and (iii) the license from Sanofi and its Affiliates to Regeneron referred to in Schedule 4 shall automatically come into full force and effect with respect to the Terminated Licensed Product(s). If Regeneron terminates this Agreement pursuant to Section 19.3, 19.4 or 19.5, or pursuant to Section 19.6(a) then Sanofi shall pay to Regeneron, in addition to any other amount payable by Sanofi to Regeneron under this Agreement, under Law, or pursuant to any contractual remedies available to Regeneron, an amount equal to one hundred percent (100%) of the Development Costs incurred by Regeneron under the Global Development Plan during the period commencing on the effective date of such termination of this Agreement pursuant to any of such Sections and ending on the twelve (12) month anniversary of such date.

(b) Upon termination of this Agreement by Regeneron pursuant to Section 19.2(b) or by Sanofi pursuant to Section 19.3 or 19.4, in its entirety, or for a particular Licensed Product or particular Licensed Products in the Field, the provisions of Schedule 5 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated Licensed Product(s) and, except to the extent required by Regeneron to fulfill its obligations pursuant to Schedule 5, (i) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate, and revert to Sanofi, (ii) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate and (iii) the license from Regeneron referred to in Schedule 5 shall come into full force and effect with respect to the Terminated Licensed Product(s)

19.8 Survival of Obligations. Except as otherwise provided in this Article XIX, or Schedule 4 or Schedule 5, upon expiration, or upon termination of this Agreement with respect to all Licensed Products in the Field, or for a particular Licensed Product or particular Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the rights and obligations of the Parties hereunder with respect to the Terminated Licensed Product(s), in the applicable country or countries if such termination is pursuant to Section 19.2(a)(ii), shall terminate, and this Agreement shall cease to be of further force or effect to the extent of such termination, provided that notwithstanding any expiration or termination of this Agreement:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3408

Samsung Bioepis Exhibit 1017, pg. 3408

(a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that Regeneron's obligations with respect to the Global Development Balance payments provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero;

(b) subject to the provisions of this Article XIX, including Schedule 4 and Schedule 5 to the extent applicable, the obligations of the Parties with respect to the protection and nondisclosure of Party Information and New Information in accordance with Article XVI, as well as other provisions (including, without limitation, Sections 7.4, 9.8, 9.9, 9.12, 10.3 and 10.4, the second sentence of Section 12.1(e) and Articles XII (with respect to Joint Inventions), XVI, XVII, XIX and XX) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable; and

(c) such expiration or termination and this Article XIX shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

ARTICLE XX
MISCELLANEOUS

20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Except as set forth in Article X, the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

20.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

20.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 6 attached hereto and shall be (a) delivered personally, (b) sent via a reputable

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3409

Samsung Bioepis Exhibit 1017, pg. 3409

nationwide overnight courier service, or (c) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, one (2) Business Days after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.

20.4 Entire Agreement. This Agreement, together with the Discovery Agreement and, solely to the extent referred to herein, the Ancillary Agreements contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof, provided that the last sentence of Section 1.41 of the Discovery Agreement shall apply with respect to any conflict or inconsistency between this Agreement and the Discovery Agreement.

20.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.

20.6 Interpretation. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) the words "herein" or "hereunder" relate to this Agreement.

20.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

20.8 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is or may be required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

20.9 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3410

Samsung Bioepis Exhibit 1017, pg. 3410

Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.10 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of Section 20.13.

20.11 Affiliates. Each Party may, and to the extent it is in the best interests of the Licensed Products in the Field in the Territory shall, perform its obligations hereunder through one or more of its Affiliates. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party the prompt and timely performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Sanofi Amerique guarantees to Regeneron the prompt and timely payment of amounts payable by Sanofi to Regeneron hereunder once those amounts have become legally due and payable. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of a Licensed Product under this Agreement, then such Party shall enter into a separate agreement with such Affiliate pursuant to which the obligations of such Party hereunder shall be binding on such Affiliate and which shall provide that the other Party is a third-party beneficiary of such agreement entitled to enforce such agreement and this Agreement against such Affiliate. Each Party represents and warrants to the other Party that it has licensed or will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

20.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

20.13 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Article XVII is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3411

Samsung Bioepis Exhibit 1017, pg. 3411

20.14 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as provided for in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.15 Limitation of Damages. IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 20.15 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD-PARTY CLAIMS .

20.16 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the Development, Manufacture or Commercialization of any Licensed Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

20.17 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.

[Remainder of page intentionally left blank; signature page follows]

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3412

Samsung Bioepis Exhibit 1017, pg. 3412

IN WITNESS WHEREOF, Sanofi, Sanofi Amerique and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMACEUTICALS INC.

By: /s/ Karen Linehan
Name: Karen Linehan
Title: Authorized Signatory

By: /s/ Robin White
Name: Robin White
Title: Authorized Signatory

SANOFI-AVENTIS AMERIQUE DU NORD
(solely for purposes of Section 15.1, 15.2 and 20.11).

By: /s/ Jean-Luc Renard
Name: Jean-Luc Renard
Title: Authorized Signatory

By: /s/ Karen Linehan
Name: Karen Linehan
Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard Schleifer
Name: Leonard Schleifer
Title: President & CEO

EXHIBIT A

Royalties For Opt-Out Products

Stage of Development at Opt-Out	Royalties on Net Sales
**********	********
**********	********

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3414

Samsung Bioepis Exhibit 1017, pg. 3414

EXHIBIT B

Summary Outline of Initial Development Plan For REGN88 (IL-6RmAb)

****

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3415

Samsung Bioepis Exhibit 1017, pg. 3415

SCHEDULE 1

Manufacturing Cost

****

1

SCHEDULE 2

Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the "Quarterly True-Up") equal to (a) the U.S. Profit Split for such Quarter payable to Regeneron (as set forth in Part I), plus (b) the Rest of World Profit Split for such Quarter payable to Regeneron (as set forth in Part II), minus (c) the Development Compensation Payment for such Quarter payable to Sanofi (as set forth in Part III), plus or minus (d) the Regeneron Reimbursement Amount for such Quarter payable to either Regeneron or Sanofi (as set forth in Part IV).

In the event that the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Sanofi to Regeneron in accordance with the terms set forth in Article 9. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Sanofi in accordance with the terms set forth in Article 9. An example of the Quarterly True-Up is shown in Part V.

I. U.S. PROFIT SPLIT

The "U.S. Profit Split" shall mean fifty percent (50%) of U.S. Profits in a Quarter. "U.S. Profits" in a Quarter shall mean aggregate Net Sales of all Licensed Products in the U.S. in the Quarter less the sum of (a) aggregate COGS in the U.S. in the Quarter, (b) aggregate Shared Commercial Expenses incurred by both Parties and allocable to the U.S. in the Quarter, and (c) aggregate Other Shared Expenses incurred by both Parties and allocable to, the U.S. in the Quarter.

An example of a calculation of the U.S. Profit Split in a Quarter would be:

****

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3417

Samsung Bioepis Exhibit 1017, pg. 3417

II. REST OF WORLD PROFIT SPLIT

The Parties intend to share profits from Net Sales of Licensed Products in the Rest of World (or ROW) in each Contract Year (the "Rest of World Profit Split," defined below) based on the aggregate amount of such Net Sales in accordance with the Target ROW Profit Split (defined below). Since the full calculation cannot be done until aggregate Net Sales for the full Contract Year are known, each Quarter, the Parties will calculate an estimated profit split for the Quarter based on Net Sales for the Quarter in ROW and the Applicable ROW Percentages (defined below). Following the end of each Contract Year, the Parties will true-up the quarterly estimates of the Rest of World Profit Split to the Target ROW Profit Split through the ROW Profit Split Annual True-Up calculation (defined below).

The "Target ROW Profit Split" for any Contract Year shall mean a profit split whereby ROW Profits from ROW Net Sales of all Licensed Products up to ******* in the Contract Year are split 65% Sanofi/35% Regeneron, and ROW Profits from ROW Net Sales of all Licensed Products from ******* up to $750 million in the Contract Year are split 60% Sanofi/40% Regeneron, and ROW Profits from ROW Net Sales of all Licensed Products greater than $750 million in the Contract Year are split 55% Sanofi/45% Regeneron, with all profit splits calculated using the assumption that the ratio of ROW Profits to ROW Net Sales is the same on each dollar of ROW Net Sales in the Contract Year.

The "Rest of World Profit Split" (or "ROW Profit Split") for a Quarter shall mean *********

The "Applicable ROW Percentages" for the Quarter for each of Sanofi and Regeneron shall mean the percentages to be used to calculate each Party's Rest of World Profit Split for the Quarter, as illustrated in the example below. At the end of each Contract Year, as part of the calculation of the fourth Quarter Rest of World Profit Split, a "ROW Profit Split Annual True-Up" shall also be calculated to make each Party's Rest of World Profit Split for the Contract Year equal to the Target ROW Profit Split. Calculation of the Applicable ROW Percentages and Rest of World Profit Splits for a Quarter and ROW Profit Split Annual True-Up for a Contract Year are illustrated in the example below.

****

Notwithstanding the method of calculation shown above, in any Quarter (or for any full Contract Year) in which the ROW Profits are negative, the Applicable ROW Percentages for such Quarter

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3418

Samsung Bioepis Exhibit 1017, pg. 3418

(or for such Contract Year after calculation of the ROW Profit Split Annual True-Up) shall be fifty-five percent (55%) for Sanofi and forty-five percent (45%) for Regeneron.

An example of a calculation of the Rest of World Profit Split in a Quarter would be:

	Aggregate	Sanofi	Regeneron
Net Sales in the ROW	*******	******	*****
COGS	*******	******	******
Shared Commercial Expenses	*******	******	****
Other Shared Expenses	*******	******	*****
ROW Profits	******	******	*****
Applicable ROW Percentages		***	***
ROW Profit Split		***	***

III. DEVELOPMENT COMPENSATION PAYMENT

The "Regeneron Profit Split" in a Quarter shall mean the sum of (a) the U.S. Profit Split for such Quarter payable to Regeneron plus (b) the Rest of World Profit Split for such Quarter payable to Regeneron.

The "Development Balance" as of the end of a Quarter shall mean **********

If both the Development Balance as of the end of a Quarter is greater than zero and the Regeneron Profit Split for the Quarter is greater than zero, the "Development Compensation Payment" for such Quarter shall equal the lower of (a) ********** and (b) the Development Balance. Otherwise, the Development Compensation Payment for the Quarter shall equal zero.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3419

Samsung Bioepis Exhibit 1017, pg. 3419

An example of a calculation of the Development Compensation Payment in a Quarter would be:

Development Balance at the end of the Quarter	***
U.S. Profit Split payable to Regeneron	***
Rest of World Profit Split payable to Regeneron	***
Regeneron Profit Split	***
*****	***
Development Compensation Payment	**

For the avoidance of doubt, the Development Costs for and Opt-Out Product until the time such Opt-Out Product becomes an Opt-Out Product are included in the calculation of the Development Balance.

IV. REGENERON REIMBURSEMENT AMOUNT

The "Regeneron Reimbursement Amount" for a Quarter shall mean *******

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Commercial Expenses in the U.S.	****
Regeneron Shared Commercial Expenses in ROW	****
Regeneron Other Shared Expenses in the U.S.	****
Regeneron Other Shared Expenses in ROW	****
Regeneron Development Costs under a Global Development Plan	****
Shared Phase 3 Trial Costs Balance	****
Regeneron Reimbursement Amount	****

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3420

Samsung Bioepis Exhibit 1017, pg. 3420

V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-Up in a Quarter would be:

U.S. Profit Split Payable to Regeneron	***
ROW Profit Split Payable to Regeneron	***
Development Compensation Payment	***
Regeneron Reimbursement Amount	****
Quarterly True-Up	***

In this example, Sanofi would pay Regeneron *** in accordance with the terms set forth in Article 9.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3421

Samsung Bioepis Exhibit 1017, pg. 3421

SCHEDULE 3

Sales Milestones

Aggregate annual Net Sales of all Licensed Products in Rest of World Countries	Sales Milestone
US$1 billion	**********
**********	**********
**********	**********
*********	*********
********	*********

For purposes of clarification, each of the foregoing milestone payments shall be made only once and only upon the first occurrence of each milestone. Aggregate annual Net Sales of Licensed Products shall be determined based on the aggregate Net Sales of all Licensed Products in Rest of World Countries in any rolling twelve (12) month period.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3422

Samsung Bioepis Exhibit 1017, pg. 3422

SCHEDULE 4

Termination Arrangements

The rights and obligations set forth in this Schedule 4 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated Licensed Product(s) as to which, and, if applicable pursuant to Section 19.2(a)(ii), only in the country or countries in which, this Agreement has been terminated.

1. Sanofi shall promptly collect and return, and cause its Affiliates and Sublicensees to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing New Information or Party Information directly related to any Terminated Licensed Product(s), and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to any Terminated Licensed Product(s). In addition, at Regeneron's request, Sanofi shall collect and transfer to Regeneron any remaining inventory of Promotional Materials, sales training materials, samples, and product inventory. Notwithstanding the foregoing, Sanofi may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Regeneron and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than any royalties due for any Royalty Products under the Discovery Agreement and any amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or Collaboration by Sanofi), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Sanofi Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing and Commercializing Terminated Licensed Product(s) in the Field in the Territory (and solely to the extent such Sanofi Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Sanofi Intellectual Property retained by Sanofi).

3. Sanofi shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture, and Commercialization of the Terminated Licensed Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Sanofi shall transfer and assign to Regeneron (or its nominee) all Marketing Approvals, Pricing Approvals, and other regulatory filings (including Registration Filings) made or obtained by Sanofi or its Affiliates or any of its Sublicensees to the extent specifically relating to the Terminated Licensed Product(s).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3423

Samsung Bioepis Exhibit 1017, pg. 3423

(b) Sanofi shall assign and transfer to Regeneron (or its nominee) Sanofi's entire right, title and interest in and to all Product Trademarks for any Terminated Licensed and Promotional Materials relating to the Terminated Licensed Product(s); provided that nothing herein is intended to convey any rights in or to Sanofi's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Sanofi shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to the Terminated Licensed Product(s) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Sanofi, or such other format as may be reasonably requested by Regeneron.

(d) Sanofi shall use Commercially Reasonable Efforts to assign to Regeneron any applicable sublicenses to the extent related to the Terminated Licensed Product(s) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory, as reasonably requested by Regeneron.

(e) Without limitation of Sanofi's other obligations under this Schedule 4, to the extent Sanofi or its Affiliate is Manufacturing (in whole or in part) the Terminated Licensed Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Sanofi (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of such Terminated Licensed Product(s), and Regeneron shall purchase such Terminated Licensed Product(s), at the same price, and on such other terms and conditions on which Sanofi was supplying, or in the absence of termination would have been required to supply, such Terminated Licensed Product(s), through the second anniversary of the effective date of termination of this Agreement with respect to such Terminated Licensed Product(s) or such shorter period if Regeneron notifies Sanofi that Regeneron is able to Manufacture or have Manufactured such Terminated Licensed Product(s) on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the development, manufacture, and commercialization of the Terminated Licensed Product(s) in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, except as expressly provided in the Discovery Agreement or this Agreement, Regeneron shall not be required to provide Sanofi any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 4; provided, however, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Sanofi may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3424

Samsung Bioepis Exhibit 1017, pg. 3424

SCHEDULE 5

Termination Arrangements

The rights and obligations set forth in this Schedule 5 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated Licensed Product(s) as to which this Agreement has been terminated.

1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Sanofi or, at Sanofi's request, destroy, all documents containing New Information or Party Information of Sanofi and its Affiliates directly related to any Opt-Out Products, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to the Terminated Licensed Product(s). In addition, at Sanofi's request, Regeneron shall collect and transfer to Sanofi any remaining inventory of Promotional Materials, sales training materials, product samples and product inventory. Notwithstanding the foregoing, Regeneron may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Sanofi and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than for amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or Collaboration by Regeneron), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Regeneron Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing, and Commercializing the Terminated Licensed Product(s) in the Field in the Territory (and solely to the extent such Regeneron Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Regeneron Intellectual Property retained by Regeneron.

3. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Sanofi to enable Sanofi (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture and Commercialization of the Terminated Licensed Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Regeneron shall transfer and assign to Sanofi (or its nominee) all Marketing Approvals, Pricing Approvals and other regulatory filings (including Registration Filings) made or obtained by Regeneron or its Affiliates or any of its sublicensees to the extent specifically relating to the Terminated Licensed Product(s).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3425

Samsung Bioepis Exhibit 1017, pg. 3425

(b) Regeneron shall assign and transfer to Sanofi (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks for the Terminated Licensed Product(s) and Promotional Materials relating to the Terminated Licensed Product(s); provided that nothing herein is intended to convey any rights in or to Regeneron's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Regeneron shall provide to Sanofi (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to the Terminated Licensed Product(s) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Regeneron, or such other format as may be reasonably requested by Sanofi.

(d) Regeneron shall use Commercially Reasonable Efforts to assign to Sanofi any applicable sublicenses to the extent related to the Terminated Licensed Product(s) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory, as reasonably requested by Sanofi.

(e) Without limitation of Regeneron's other obligations under this Schedule 5, to the extent Regeneron or its Affiliate is Manufacturing (in whole or in part) the Terminated Licensed Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Regeneron (or its Affiliate) will perform such Manufacturing responsibilities and supply Sanofi with Clinical Supply Requirements and/or Commercial Supply Requirements of such Terminated Licensed Product(s), and Sanofi shall purchase such Terminated Licensed Product(s), at the same price, and on such other terms and conditions on which Regeneron was supplying, or in the absence of termination would have been required to supply, such Terminated Licensed Product(s), through the second anniversary of the effective date of termination of this Agreement with respect to such Terminated Licensed Product(s) or such shorter period if Sanofi notifies Regeneron that Sanofi is able to Manufacture or have Manufactured such Terminated Licensed Product(s) on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Terminated Licensed Product(s) in the Field hereunder to Sanofi (or its Sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, Sanofi shall not be required to provide Regeneron any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 5; provided, however, that Sanofi shall be solely responsible for paying any royalties, fees or other consideration that Regeneron may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Sanofi of such licenses or other rights.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3426

Samsung Bioepis Exhibit 1017, pg. 3426

SCHEDULE 6

Notices

(a) If to Sanofi or Sanofi Amerique:

Aventis Pharmaceuticals Inc
200 Crossing Boulevard
Bridgewater
New Jersey 08807
USA
Attention: President R&D
Copy: General Counsel

With a copy to:

sanofi-aventis
174 Avenue de France
Paris, France 75017
Attention: General Counsel

(b) If to Regeneron:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
U.S.A.
Attention: President Copy: General Counsel

With a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street, 31st Floor
Boston, Massachusetts 02108
Attention: Kent A. Coit

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3427

Samsung Bioepis Exhibit 1017, pg. 3427

Exhibit 10.20

STOCK PURCHASE AGREEMENT

By and Among

SANOFI-AVENTIS AMÉRIQUE DU NORD,

SANOFI-AVENTIS US LLC

AND

REGENERON PHARMACEUTICALS, INC.

Dated as of November 28, 2007

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3428

Samsung Bioepis Exhibit 1017, pg. 3428

TABLE OF CONTENTS

	Page
1. DEFINITIONS	1
1.1 Defined Terms	1
1.2 Additional Defined Terms	4
2. PURCHASE AND SALE OF COMMON STOCK	4
3. CLOSING DATE; DELIVERIES	5
3.1 Closing Date	5
3.2 Deliveries	5
4. REPRESENTATIONS AND WARRANTIES OF THE COMPANY	6
4.1 Organization, Good Standing and Qualification	6
4.2 Capitalization and Voting Rights	6
4.3 Subsidiaries	7
4.4 Authorization	7
4.5 No Defaults	7
4.6 No Conflicts	7
4.7 No Governmental Authority or Third Party Consents	8
4.8 Valid Issuance of Shares	8
4.9 Litigation	8
4.10 Licenses and Other Rights; Compliance with Laws	8
4.11 Company SEC Documents; Financial Statements; Nasdaq Stock Market	8
4.12 Absence of Certain Changes	9
4.13 Internal Controls; Disclosure Controls and Procedures	9
4.14 Intellectual Property	10
4.15 Offering	10
4.16 No Integration	10
4.17 Brokers' or Finders' Fees	10
4.18 Not Investment Company	10
5. REPRESENTATIONS AND WARRANTIES OF THE INVESTOR	10
5.1 Organization; Good Standing	10
5.2 Authorization	11

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3429

Samsung Bioepis Exhibit 1017, pg. 3429

5.3 No Conflicts 11
5.4 No Governmental Authority or Third Party Consents 11
5.5 Purchase Entirely for Own Account 11
5.6 Disclosure of Information 12
5.7 Investment Experience and Accredited Investor Status 12
5.8 Acquiring Person 12
5.9 Restricted Securities 12
5.10 Legends 12
5.11 Financial Assurances 13
6. COVENANTS OF THE COMPANY 13
6.1 Conduct of the Business Pending Closing 13
6.2 Use of Proceeds 13
7. INVESTOR'S CONDITIONS TO CLOSING 13
7.1 Representations and Warranties 13
7.2 Covenants 14
7.3 Investor Agreement 14
7.4 Discovery Agreement; Sanofi License and Collaboration Agreement 14
7.5 No Material Adverse Effect 14
8. COMPANY'S CONDITIONS TO CLOSING 14
8.1 Representations and Warranties 14
8.2 Covenants 14
8.3 Investor Agreement 14
8.4 Discovery Agreement; Sanofi License and Collaboration Agreement 14
9. MUTUAL CONDITIONS TO CLOSING 15
9.1 HSR Act and Other Qualifications 15
9.2 Absence of Litigation 15
9.3 No Prohibition 15
10. TERMINATION 15
10.1 Ability to Terminate 15
10.2 Effect of Termination 16
11. ADDITIONAL COVENANTS AND AGREEMENTS 17
11.1 Legending of Existing Shares 17
11.2 Amendment of Aventis Agreement 17

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3430

Samsung Bioepis Exhibit 1017, pg. 3430

11.3 Market Listing 18
11.4 Notification under the HSR Act 18
11.5 Assistance and Cooperation 18
11.6 Effect of Waiver of Condition to Closing 19
12. MISCELLANEOUS 19
12.1 Governing Law; Submission to Jurisdiction 19
12.2 Waiver 19
12.3 Notices 20
12.4 Entire Agreement 20
12.5 Amendments 20
12.6 Headings; Nouns and Pronouns; Section References 20
12.7 Severability 20
12.8 Assignment 20
12.9 Successors and Assigns 21
12.10 Counterparts 21
12.11 Third Party Beneficiaries 21
12.12 No Strict Construction 21
12.13 Survival of Warranties 21
12.14 Remedies 21
12.15 Expenses 21

Exhibit A – Form of Cross Receipt
Exhibit B – Form of Investor Agreement
Exhibit C – Conduct of the Business Pending Closing
Exhibit D – Notices

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3431

Samsung Bioepis Exhibit 1017, pg. 3431

Exhibit 10.20

STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "Agreement"), dated as of November 28, 2007, by and among sanofi-aventis Amérique du Nord (the "Investor"), a *société en nom collectif* organized under the laws of France and wholly owned by sanofi-aventis, a company organized under the laws of France ("sanofi-aventis"), with its principal headquarters at 174, avenue de France, 75013 Paris, France, sanofi-aventis US LLC (solely for purposes of Sections 5.11, 8.2, 8.3, 11.2 and 12.13), a Delaware limited liability company indirectly wholly owned by the Investor ("Sanofi US") and the successor in interest to Aventis Pharmaceuticals Inc., a Delaware corporation indirectly wholly owned by the Investor ("Aventis"), with respect to the Aventis Collaboration Agreement, with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 00807, and Regeneron Pharmaceuticals, Inc. (the "Company"), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value $0.001 per share, of the Company (the "Common Stock").

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor, Sanofi US and the Company agree as follows:

1. Definitions.

1.1 Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside of the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the

Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

"Agreement" shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.

"Aventis Collaboration Agreement" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Sanofi US (as successor in interest to Aventis) and the Company, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, Section 11.2 of this Agreement, and as further amended from time to time.

"Business Day" shall mean a day on which commercial banking institutions in New York, New York are open for business.

"Collaboration Agreements" means, collectively, the Aventis Collaboration Agreement, the Discovery Agreement and the Sanofi License and Collaboration Agreement.

"Cross Receipt" shall mean an executed document signed by each of the Company and the Investor, in substantially the form of Exhibit A attached hereto.

"Discovery Agreement" shall mean that certain Discovery and Preclinical Development Agreement between the Company and Aventis dated as of the date hereof, as the same may be amended from time to time.

"Effect" shall have the meaning set forth in the definition of "Material Adverse Effect."

"Governmental Authority" shall mean any court, agency, authority, department or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.

"Intellectual Property" shall mean shall mean trademarks, trade names, trade dress, service marks, copyrights, and similar rights (including registrations and applications to register or renew the registration of any of the foregoing), patents and patent applications, trade secrets, and any other similar intellectual property rights.

"Intellectual Property License" shall mean any license, permit, authorization, approval, contract or consent granted, issued by or with any Person relating to the use of Intellectual Property.

"Investor Agreement" shall mean that certain Investor Agreement among sanofi-aventis, Sanofi US, Aventis, the Investor and the Company, to be dated as of the Closing Date, in substantially the form of Exhibit B attached hereto, as the same may be amended from time to time.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3433

Samsung Bioepis Exhibit 1017, pg. 3433

"Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

"Material Adverse Effect" shall mean any change, event or occurrence (each, an "Effect") that, individually or when taken together with all other Effects, has (i) a material adverse effect on the business, financial condition, results of operations or prospects of the Company and its subsidiaries, taken as a whole, or (ii) a material adverse effect on the Company's ability to perform its obligations, or consummate the Transaction, in accordance with the terms of this Agreement, except in the case of (i) or (ii) to the extent that any such Effect results from or arises out of: (A) changes in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (B) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles in the United States or interpretations thereof that, in each case, generally affect the biotechnology or biopharmaceutical industries, (C) the announcement, pendency or performance of this Agreement, the Discovery Agreement or the Sanofi License and Collaboration Agreement, or the consummation of the Transaction or the identity of the Investor, (D) any change in the trading prices or trading volume of the Common Stock (it being understood that the facts giving rise to or contributing to any such change may be deemed to constitute, or be taken into account when determining whether there has been or will be, a Material Adverse Effect, except to the extent any of such facts is an Effect referred in clauses (A) through (J) of this definition), (E) acts of war, sabotage or terrorism, or any escalation or worsening of any such acts of war, sabotage or terrorism, (F) earthquakes, hurricanes, floods or other natural disasters, (G) any action taken by the Company contemplated by this Agreement or in accordance with any of the Collaboration Agreements or with the Investor's written consent, (H) any breach, violation or non-performance by the Investor or any of its Affiliates under any of the Collaboration Agreements, or (I) shareholder litigation arising out of or in connection with the execution, delivery or performance of the Transaction Agreements, the Discovery Agreement or the Sanofi License and Collaboration Agreement; provided, that with respect to clauses (A), (B), (E) and (F) such Effect does not have a materially disproportionate and adverse effect on the Company relative to most other comparable companies and their respective subsidiaries, taken as a whole, in the biotechnology or biopharmaceutical industries.

"Organizational Documents" shall mean (i) the Restated Certificate of Incorporation of the Company as of June 21, 1991, as amended through the date of this Agreement and (ii) the By-Laws of the Company, as amended through the date of this Agreement.

"Person" shall mean any individual, partnership, limited liability company, firm, corporation, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

"Sanofi License and Collaboration Agreement" shall mean that certain License and Collaboration Agreement between the Company, the Investor and Aventis dated as of the date hereof.

"Third Party" shall mean any Person (other than a Governmental Authority) other than the Investor, the Company or any Affiliate of the Investor or the Company.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3434

Samsung Bioepis Exhibit 1017, pg. 3434

"Transaction" means the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor, in accordance with the terms hereof.

"Transaction Agreements" shall mean this Agreement and the Investor Agreement.

1.2 Additional Defined Terms. In addition to the terms defined in Section 1.1, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

Defined Term	Section
Aggregate Purchase Price	Section 2
Aventis	Preamble
Class A Stock	Section 4.2(a).
Closing	Section 3.1
Closing Date	Section 3.1
Common Stock	Preamble
Company	Preamble
Company SEC Documents	Section 4.11(a)
Exchange Act	Section 4.11(a)
Final Termination Date	Section 10.1(b)
HSR Act	Section 4.7
Investor	Preamble
LAS	Section 4.7
Modified Clause	Section 12.7
Permits	Section 4.10
Original Termination Date	Section 10.1(b)
Sanofi US	Preamble
sanofi-aventis	Preamble
SEC	Section 4.7
Securities Act	Section 4.11(a)
Share Amount	Section 2
Shares	Section 2

2. Purchase and Sale of Common Stock. Subject to the terms and conditions of this Agreement, at the Closing, the Company shall issue and sell to the Investor, free and clear of all liens, other than any liens arising as a result of any action by the Investor, and the Investor shall purchase from the Company, a number of shares of Common Stock equal to the Share Amount (the "Shares"), for an aggregate purchase price of US $312,000,000.00. (the "Aggregate Purchase Price"). The "Share Amount" shall equal 12,000,000; provided, however, that in the event of any stock dividend, stock split, combination of shares, recapitalization or other similar change in the capital structure of the Company after the date hereof and on or prior to the Closing which affects or relates to the Common Stock, the Share Amount shall be adjusted proportionately.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3435

Samsung Bioepis Exhibit 1017, pg. 3435

3. Closing Date; Deliveries.

3.1 Closing Date. Subject to the satisfaction or waiver of all the conditions to the Closing set forth in Sections 7, 8 and 9 hereof, the closing of the purchase and sale of the Shares hereunder (the "Closing") shall be held on the third (3rd) Business Day after the satisfaction of the conditions to Closing set forth in Sections 7, 8 and 9 (other than those conditions that by their nature are to be satisfied at the Closing), at 10:00 a.m. New York City time, at the offices of Skadden, Arps, Slate, Meagher & Flom LLP, 4 Times Square, New York, New York 10036, or at such other time, date and location as the parties may agree in writing. The date the Closing occurs is hereinafter referred to as the "Closing Date."

3.2 Deliveries.

(a) Deliveries by the Company. At the Closing, the Company shall deliver to the Investor a stock certificate, registered in the name of the Investor, representing the Shares, and the Company shall instruct its transfer agent to register such issuance at the time of such issuance. The Company shall also deliver at the Closing: (i) a duly executed Cross Receipt; (ii) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 7 and 9.3(b) of this Agreement have been fulfilled; (iii) a duly executed Investor Agreement; and (iv) a certificate of the secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the By-Laws of the Company as in effect on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board of Directors of the Company authorizing the execution, delivery and performance of the Transaction Agreements and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the Company's Restated Certificate of Incorporation as in effect on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing a Transaction Agreement on behalf of the Company.

(b) Deliveries by the Investor. At the Closing, the Investor shall deliver to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than three (3) Business Days before the Closing Date. The Investor shall also deliver, or cause to be delivered, at the Closing: (i) a duly executed Cross Receipt; (ii) a certificate in form and substance reasonably satisfactory to the Company duly executed by an authorized executive officer of the Investor certifying that the conditions to Closing set forth in Section 8 of this Agreement have been fulfilled; (iii) an Investor Agreement, duly executed by sanofi-aventis, Sanofi US, Aventis and the Investor; and (iv) a certificate of the secretaries of sanofi-aventis, Sanofi US, Aventis and the Investor dated as of the Closing Date certifying (A) that attached thereto are true and complete copies of any and all organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents) of each of sanofi-aventis, Sanofi US, Aventis and the Investor, as applicable, as in effect on the Closing Date; and (B) as to the incumbency and specimen signature of any officer executing a Transaction Agreement on behalf of sanofi-aventis, Sanofi US, Aventis or the Investor, as applicable.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3436

Samsung Bioepis Exhibit 1017, pg. 3436

4. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that:

4.1 Organization, Good Standing and Qualification.

(a) The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of New York. The Company has all requisite corporate power and corporate authority to own, lease and operate its properties and assets, to carry on its business as now conducted, and as proposed to be conducted as described in the Company SEC Documents, to enter into the Transaction Agreements to issue and sell the Shares and to carry out the other transactions contemplated by the Transaction Agreements.

(b) The Company is qualified to transact business and is in good standing in each jurisdiction in which the character of the properties owned, leased or operated by the Company or the nature of the business conducted by the Company makes such qualification necessary, except where the failure to be so qualified would not have a Material Adverse Effect.

4.2 Capitalization and Voting Rights.

(a) The authorized capital of the Company as of the date hereof consists of: (i) 160,000,000 shares of Common Stock of which, as of the date of this Agreement, (w) 63,932,731 shares are issued and outstanding, (x) 2,260,266 shares are reserved for issuance upon conversion of the Company's Class A Stock, par value $0.001 per share (the "Class A Stock"), each share of Class A Stock being convertible into one (1) share of Common Stock, (y) 18,843,943 shares are reserved for issuance pursuant to the Company's 2000 Long-Term Incentive Plan, of which 15,244,146 shares are issuable upon the exercise of stock options outstanding on the date hereof, and (z) 6,611,300 shares are reserved for issuance upon conversion of the Company's 5½% Convertible Senior Subordinated Notes due 2008; (ii) 40,000,000 shares of Class A Stock of which, as of the date of this Agreement, 2,260,266 shares are issued and outstanding and 44,246 shares are reserved for issuance pursuant to the Company's 1989 Executive Stock Purchase Plan; and (iii) 30,000,000 shares of preferred stock, par value $0.01 per share, of which no shares are issued and outstanding as of the date of this Agreement. All of the issued and outstanding shares of Common Stock and Class A Stock (A) have been duly authorized and validly issued, (B) are fully paid and non-assessable and (C) were issued in compliance with all applicable federal and state securities Laws and not in violation of any preemptive rights.

(b) All of the authorized shares of Common Stock are entitled to one (1) vote per share. All of the authorized shares of Class A Stock are entitled to ten (10) votes per share.

(c) Except as described or referred to in Section 4.2(a) above, as of the date hereof, there are not: (i) any outstanding equity securities, options, warrants, rights (including conversion or preemptive rights) or other agreements pursuant to which the Company is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of the Company or (ii) except as set forth in the Investor Agreement, any restrictions on the transfer of capital stock of the Company other than pursuant to state and federal securities Laws.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3437

Samsung Bioepis Exhibit 1017, pg. 3437

(d) Except as provided in the Investor Agreement, the Company is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a stockholder or director of the Company.

4.3 Subsidiaries. The Company does not have any subsidiaries required to be disclosed in an exhibit to its Annual Report on Form 10-K pursuant to Item 601(b)(21) of Regulation S-K.

4.4 Authorization.

(a) All requisite corporate action on the part of the Company, its directors and stockholders required by applicable Law or, assuming the accuracy of the Investor's representation in Section 5.8, The NASDAQ Stock Market LLC for the authorization, execution and delivery by the Company of the Transaction Agreements and the performance of all obligations of the Company hereunder and thereunder, including the authorization, issuance and delivery of the Shares, has been taken.

(b) This Agreement has been, and upon the execution and delivery of the Investor Agreement by the Company at the Closing, the Investor Agreement will be, duly executed and delivered by the Company, and upon the due execution and delivery of this Agreement by the Investor and Sanofi US, this Agreement will constitute, and upon the due execution and delivery of the Investor Agreement by sanofi-aventis, Sanofi US, Aventis and the Investor, the Investor Agreement will constitute, valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms (except as such enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (ii) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

4.5 No Defaults. The Company is not in default under or in violation of (a) its Organizational Documents, (b) any provision of applicable Law or any ruling, writ, injunction, order, Permit, judgment or decree of any Governmental Authority or (c) any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound, except, in the case of subsections (b) and (c), as would not have a Material Adverse Effect. To the knowledge of the Company, there exists no condition, event or act which after notice, lapse of time, or both, would constitute a default or violation by the Company under any of the foregoing, except, in the case of subsections (b) and (c), as would not have a Material Adverse Effect.

4.6 No Conflicts. The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Company do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound or (c)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3438

Samsung Bioepis Exhibit 1017, pg. 3438

violate or conflict with any of the provisions of the Company's Organizational Documents, except, in the case of subsections (a) and (b), as would not have a Material Adverse Effect.

4.7 No Governmental Authority or Third Party Consents. No consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by the Company in connection with the authorization, execution and delivery by the Company of any of the Transaction Agreements or with the authorization, issue and sale by the Company of the Shares, except (i) such filings as may be required to be made with the Securities and Exchange Commission (the "SEC") and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws, (ii) as required pursuant to the Hart-Scott-Rodino Antitrust Improvements Act, as amended (the "HSR Act") and (iii) with respect to the Shares, the filing with The NASDAQ Stock Market LLC of, and the absence of unresolved issues with respect to, a Notification Form: Listing of Additional Shares (the "LAS").

4.8 Valid Issuance of Shares. When issued, sold and delivered at the Closing in accordance with the terms hereof for the Aggregate Purchase Price, the Shares shall be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal or other similar rights, other than as arising pursuant to the Transaction Agreements, as a result of any action by the Investor or under federal or state securities Laws.

4.9 Litigation. Except as set forth in the Company SEC Documents filed prior to the date of this Agreement, there is no action, suit, proceeding or investigation pending (of which the Company has received notice or otherwise has knowledge) or, to the Company's knowledge, threatened, against the Company or which the Company intends to initiate which has had or is reasonably likely to have a Material Adverse Effect.

4.10 Licenses and Other Rights; Compliance with Laws. The Company has all franchises, permits, licenses and other rights and privileges ("Permits") necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, except where the failure to be in compliance does not and would not have a Material Adverse Effect. To the Company's knowledge, it has not taken any action that would interfere with the Company's ability to renew all such Permit(s), except where the failure to renew such Permit(s) would not have a Material Adverse Effect. The Company is and has been in compliance with all Laws applicable to its business, properties and assets, and to the products and services sold by it, except where the failure to be in compliance does not and would not have a Material Adverse Effect.

4.11 Company SEC Documents; Financial Statements; Nasdaq Stock Market.

(a) Since December 31, 2006, the Company has timely filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein), and any required amendments to any of the foregoing, with the SEC (the "Company SEC Documents"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3439

Samsung Bioepis Exhibit 1017, pg. 3439

1934, as amended (the "Exchange Act"), and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and in its quarterly reports on Form 10-Q for the quarterly periods ended September 30, 2007, June 30, 2007, and March 31, 2007 comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended. Except (i) as set forth in the Company SEC Documents or (ii) for liabilities incurred in the ordinary course of business subsequent to the date of the most recent balance sheet contained in the Company SEC Documents, the Company has no liabilities, whether absolute or accrued, contingent or otherwise, other than those that would not, individually or in the aggregate, have a Material Adverse Effect.

(c) As of the date of this Agreement, the Common Stock is listed on The Nasdaq Global Market, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from The Nasdaq Global Market. As of the date of this Agreement, the Company has not received any notification that, and has no knowledge that, the SEC or The NASDAQ Stock Market LLC is contemplating terminating such listing or registration.

4.12 Absence of Certain Changes. Except as disclosed in the Company SEC Documents, since December 31, 2006, there has not occurred any event that has caused or would reasonably be expected to cause a Material Adverse Effect.

4.13 Internal Controls; Disclosure Controls and Procedures. The Company maintains internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. The Company has implemented the "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) required in order for the Chief Executive Officer and Chief Financial Officer of the Company to engage in the review and evaluation process mandated by the Exchange Act, and is in compliance with such disclosure controls and procedures in all material respects. Each of the Chief Executive Officer and the Chief Financial Officer of the Company (or each former Chief Executive Officer of the Company and each former Chief Financial Officer of the Company, as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 with respect to all reports, schedules, forms, statements and other documents required to be filed by the Company with the SEC.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3440

Samsung Bioepis Exhibit 1017, pg. 3440

4.14 Intellectual Property. The Intellectual Property that is owned by the Company is owned free from any liens or restrictions, and all of the Company's material Intellectual Property Licenses are in full force and effect in accordance with their terms, and are free of any liens or restrictions, except (a) where the failure to be free from such liens or restrictions would not have a Material Adverse Effect or (b) as set forth in any such Intellectual Property License. Except as set forth in the Company SEC Documents, there is no legal claim or demand of any Person pertaining to, or any proceeding which is pending (of which the Company has received notice or otherwise has knowledge) or, to the knowledge of the Company, threatened, (i) challenging the right of the Company in respect of any Company Intellectual Property, or (ii) that claims that any default exists under any Intellectual Property License, except, in the case of (i) and (ii) above, where any such claim, demand or proceeding would not have a Material Adverse Effect.

4.15 Offering. Subject to the accuracy of the Investor's representations set forth in Sections 5.5, 5.6, 5.7, 5.9 and 5.10, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption.

4.16 No Integration. The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act) which is or will be integrated with the Shares sold pursuant to this Agreement in a manner that would require the registration of the Shares under the Securities Act.

4.17 Brokers' or Finders' Fees. No broker, finder, investment banker or other Person is entitled to any brokerage, finder's or other fee or commission from the Company in connection with the transactions contemplated by the Transaction Agreements.

4.18 Not Investment Company. The Company is not, and solely after receipt of the Aggregate Purchase Price and application of such proceeds in substantially the manner described under "Use of Proceeds" in the Company's prospectus supplement filed November 15, 2006 with the SEC, will not be, an "investment company" as defined in the Investment Company Act of 1940, as amended.

5. Representations and Warranties of the Investor. The Investor hereby represents and warrants to the Company as set forth in Sections 5.1 through 5.10 (on behalf of itself, Sanofi US, Aventis and sanofi-aventis), and the Investor and Sanofi US hereby jointly and severally represent and warrant to the Company as set forth in Section 5.11, that:

5.1 Organization; Good Standing. The Investor is a partnership duly organized, validly existing and in good standing under the laws of France. Sanofi US is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware. Aventis is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. sanofi-aventis is a company duly organized, validly existing and in good standing under the laws of France. Each of the Investor and Sanofi US has, and Aventis and sanofi-aventis will have, all requisite power and authority to enter into the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3441

Samsung Bioepis Exhibit 1017, pg. 3441

Transaction Agreements to which it is or will be a party, in the case of the Investor to purchase the Shares and, in the case of the Investor, Sanofi US, Aventis and sanofi-aventis, to perform its respective obligations under and to carry out the other transactions contemplated by the Transaction Agreements to which it is or will be a party.

5.2 Authorization. All requisite action on the part of the Investor, Sanofi US, Aventis, sanofi-aventis and their respective directors and stockholders, required by applicable Law for the authorization, execution and delivery by the Investor, Sanofi US, Aventis and sanofi-aventis of the Transaction Agreements to which they are a party, and the performance of all of their respective obligations thereunder, including the subscription for and purchase of the Shares, has been taken or, in the case of Aventis and sanofi-aventis, will be taken prior to the Closing. This Agreement, and upon the execution and delivery of the Investor Agreement at the Closing by the Investor, Sanofi US, Aventis and sanofi-aventis, the Investor Agreement will be, duly executed and delivered by, as applicable, the Investor, Sanofi US, Aventis and sanofi-aventis and upon the due execution and delivery thereof by the Company, will constitute valid and legally binding obligations of, as applicable, the Investor, Sanofi US, Aventis and sanofi-aventis, enforceable against, as applicable, the Investor, Sanofi US, Aventis and sanofi-aventis in accordance with their respective terms (except as such enforceability may be limited by (a) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (b) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

5.3 No Conflicts. The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Investor, Sanofi US, Aventis and sanofi-aventis, do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Investor, Sanofi US, Aventis or sanofi-aventis or any of their respective assets, are bound, or (c) violate or conflict with any of the provisions of the Investor's, Sanofi US', Aventis' or sanofi-aventis' organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents), except as would not impair or adversely affect the ability of the Investor, Sanofi US, Aventis or sanofi-aventis, as applicable, to consummate the Transactions and perform their respective obligations under the Transaction Agreements and except, in the case of subsections (a) and (b) as would not have a material adverse effect on the Investor, Sanofi US, Aventis or sanofi-aventis.

5.4 No Governmental Authority or Third Party Consents. No consent, approval, authorization or other order of any Governmental Authority or other Third Party is required to be obtained by the Investor, Sanofi US, Aventis or sanofi-aventis in connection with the authorization, execution and delivery of any of the Transaction Agreements or with the subscription for and purchase of the Shares, except as required pursuant to the HSR Act.

5.5 Purchase Entirely for Own Account. The Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3442

Samsung Bioepis Exhibit 1017, pg. 3442

resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation or otherwise distributing the Shares. The Investor does not have and will not have as of the Closing any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to a Person any of the Shares.

5.6 Disclosure of Information. The Investor has received all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.

5.7 Investment Experience and Accredited Investor Status. The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.

5.8 Acquiring Person. As of the date of this Agreement and immediately prior to the Closing, (a) sanofi-aventis together with its Affiliates, beneficially own and will beneficially own (as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership) 2,799,552 shares of Common Stock, and (b) neither sanofi-aventis nor any of its Affiliates beneficially owns, or will beneficially own (as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership), any other securities of the Company.

5.9 Restricted Securities. The Investor understands that the Shares, when issued, shall be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, the Investor represents that it is familiar with Rule 144 of the Securities Act, as presently in effect.

5.10 Legends. The Investor understands that the certificates representing the Shares shall bear the following legends:

(a) "These securities have not been registered under the Securities Act of 1933. They may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to the securities under the Securities Act or an opinion of counsel (which counsel shall be reasonably satisfactory to Regeneron Pharmaceuticals, Inc.) that such registration is not required or unless sold pursuant to Rule 144 of the Securities Act.";

(b) any legend required by applicable state securities Laws; and

(c) "The securities represented by this certificate are subject to and shall be transferable only upon the terms and conditions of an Investor Agreement dated as of [ ], 2007,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3443

Samsung Bioepis Exhibit 1017, pg. 3443

by and among Regeneron Pharmaceuticals, Inc. and the other parties signatory thereto, a copy of which is on file with the Secretary of Regeneron Pharmaceuticals, Inc."

5.11 Financial Assurances. As of the date hereof and as of the Closing Date, the Investor has and will have access to cash in an amount sufficient to pay to the Company the Aggregate Purchase Price.

6. Covenants of the Company.

6.1 Conduct of the Business Pending Closing. During the period from the date hereof until the Closing, except as (a) set forth on Exhibit C attached hereto, (b) consented to in writing by the Investor (which consent shall not be unreasonably withheld, conditioned or delayed) or (c) otherwise contemplated by this Agreement or any of the Collaboration Agreements, the Company shall (i) operate its business only in the ordinary course, (ii) maintain its existence under applicable Law, (iii) use commercially reasonable efforts to maintain and enforce its material Intellectual Property, (iv) pay all applicable material taxes when due and payable and (v) (A) not declare, set aside or pay any dividend or make any other distribution or payment (whether in cash, stock or property or any combination thereof) in respect of its capital stock, (B) not make any other actual, constructive or deemed distribution in respect of any shares of its capital stock or otherwise make any payments to stockholders in their capacity as such and (C) not redeem, repurchase or otherwise acquire any securities of the Company or any of its subsidiaries.

6.2 Use of Proceeds. From and after the Closing Date, the Company shall use the Aggregate Purchase Price in substantially the manner described under "Use of Proceeds" in the Company's prospectus supplement filed November 15, 2006 with the SEC.

7. Investor's Conditions to Closing. The Investor's obligation to purchase the Shares at the Closing is subject to the fulfillment as of such Closing of the following conditions (unless waived in writing by the Investor):

7.1 Representations and Warranties. (a) The representations and warranties made by the Company in Section 4 hereof shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date; (b) the representations and warranties made by the Company in Article 8 of the Discovery Agreement (other than Section 8.1(a) thereof) shall be true and correct as of the date of the Discovery Agreement and as of the Closing Date as though made on and as of such Closing Date; and (c) the representations and warranties made by the Company in Article XV of the Sanofi License and Collaboration Agreement (other than Section 15.1(a) thereof) shall be true and correct as of the date of the Sanofi License and Collaboration Agreement and as of the Closing Date as though made on and as of such Closing Date, except in the case of subsections (a), (b) and (c) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 7.1, all such representations and warranties of the Company (other than Sections 4.1(a), 4.2, 4.3, 4.4(a) and 4.8 of this Agreement, Section 8.1(b) of the Discovery Agreement and Section 15.1(b) of the Sanofi License and Collaboration Agreement) shall be deemed to be true and correct for purposes of this Section 7.1 unless the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3444

Samsung Bioepis Exhibit 1017, pg. 3444

failure or failures of such representations and warranties to be so true and correct, without regard to any "material," "materiality" or "Material Adverse Effect" qualifiers set forth therein (other than any reference to "material" in Sections 4.11(a) and 4.11(b)), individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

7.2 Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.

7.3 Investor Agreement. The Company shall have duly executed and delivered to the Investor, pursuant to Section 3.2(a) of this Agreement, the Investor Agreement, and (subject to execution by sanofi-aventis, Sanofi US, Aventis and the Investor) such agreement shall be in full force and effect.

7.4 Discovery Agreement; Sanofi License and Collaboration Agreement. The Company shall have duly executed and delivered to the Investor the Discovery Agreement and the Sanofi License and Collaboration Agreement, and there shall have been no termination of either of the Discovery Agreement or the Sanofi License and Collaboration Agreement that, as of the Closing, is effective.

7.5 No Material Adverse Effect. From and after the date of this Agreement until the Closing Date, there shall have occurred no event that has caused or would reasonably be expected to cause a Material Adverse Effect.

8. Company's Conditions to Closing. The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of such Closing of the following conditions (unless waived in writing by the Company):

8.1 Representations and Warranties. The representations and warranties made by the Investor (on its own behalf and on behalf of Sanofi US, Aventis and sanofi-aventis) and by Sanofi US (a) in Section 5 hereof (other than Sections 5.4 and 5.6 hereof) shall be true and correct and (b) in Sections 5.4 and 5.6 hereof shall be true and correct in all material respects, in each case as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date).

8.2 Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Investor or Sanofi US as applicable, on or prior to the Closing Date shall have been performed or complied with in all material respects.

8.3 Investor Agreement. sanofi-aventis, Sanofi US, Aventis and Investor shall have duly executed and delivered to the Company, pursuant to Section 4.2(b) of this Agreement, the Investor Agreement, and (subject to execution by the Company) such agreement shall be in full force and effect.

8.4 Discovery Agreement; Sanofi License and Collaboration Agreement. Sanofi US, Aventis and the Investor, as applicable, shall have duly executed and delivered to the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3445

Samsung Bioepis Exhibit 1017, pg. 3445

Company the Discovery Agreement and the Sanofi License and Collaboration Agreement, and there shall have been no termination of either of the Discovery Agreement or the Sanofi License and Collaboration Agreement that, as of the Closing, is effective. The Company shall have received from Aventis the payment required by Section 4.1 of the Discovery Agreement.

9. Mutual Conditions to Closing. The obligations of the Investor and the Company to consummate the Closing is subject to the fulfillment as of the Closing Date of the following conditions:

9.1 HSR Act and Other Qualifications. The filings required under the HSR Act in connection with this Agreement shall have been made and the required waiting period shall have expired or been terminated as of the Closing Date, and all other authorizations, consents, waivers, permits, approvals, qualifications and registrations to be obtained or effected with any Governmental Authority, including, without limitation, necessary blue sky permits and qualifications required by any state for the offer and sale to the Investor of the Shares, shall have been duly obtained and shall be in effect as of the Closing Date.

9.2 Absence of Litigation. There shall be no action, suit, proceeding or investigation by a Governmental Authority pending or currently threatened in writing against the Company, the Investor, Sanofi US, Aventis or sanofi-aventis which questions the validity of any of the Transaction Agreements, the right of the Company, the Investor, Sanofi US, Aventis or sanofi-aventis to enter into any Transaction Agreement or to consummate the transactions contemplated hereby or thereby or which, if determined adversely, would impose substantial monetary damages on the Company, the Investor, Sanofi US, Aventis or sanofi-aventis as a result of the consummation of the transactions contemplated by any Transaction Agreement.

9.3 No Prohibition. (a) No provision of any applicable Law and no judgment, injunction (preliminary or permanent), order or decree that prohibits, makes illegal or enjoins the consummation of the Transaction shall be in effect; and (b) there shall be no unresolved issues with The NASDAQ Stock Market LLC with respect to the LAS.

10. Termination.

10.1 Ability to Terminate. This Agreement may be terminated at any time prior to the Closing by:

(a) mutual written consent of the Company and the Investor;

(b) either the Company or the Investor, upon written notice to the other no earlier than three (3) Business Days after January 31, 2008 (the "Original Termination Date"), if the Original Termination Date cannot be or has not been validly extended pursuant to this Section 10.1(b), and if the Transaction shall not have been consummated by the Original Termination Date; provided, however, that the Original Termination Date may be extended to March 31, 2008 (the "Final Termination Date") by either the Company or the Investor, upon written notice to the other on or within two (2) Business Days after the Original Termination Date, if the Transaction shall not have been consummated by the Original Termination Date solely as the result of a failure to satisfy the condition set forth in Section 9.1 as of the Original Termination Date; provided further, however, that the right to terminate this Agreement under

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3446

Samsung Bioepis Exhibit 1017, pg. 3446

this Section 10.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Original Termination Date or the Final Termination Date, as applicable;

(c) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 9 shall have become incapable of fulfillment by the Original Termination Date or, if the Original Termination Date has been validly extended pursuant to Section 10.1(b), the Final Termination Date, and shall not have been waived in writing by the other party; provided, however, that the right to terminate this Agreement under this Section 10.1(c) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Original Termination Date or the Final Termination Date, as applicable;

(d) the Company, upon written notice to the Investor, so long as the Company is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 7.1 or 7.2, as applicable, could not be satisfied by the Closing Date, (i) upon a breach of any covenant or agreement on the part of the Investor set forth in this Agreement, or (ii) if any representation or warranty of the Investor or Sanofi US shall have been or become untrue, in each case such that any of the conditions set forth in Section 8.1, 8.2, 8.3 or 8.4, as applicable, could not be satisfied by the Closing Date;

(e) the Company, upon written notice to the Investor, if the Investor or any of its Affiliates has breached Section 20.16 of the Aventis Collaboration Agreement (for avoidance of doubt, the Company shall not have the right to terminate this Agreement as a result of a de minimis breach of Section 20.16(a) of the Aventis Collaboration Agreement or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 20.16 of the Aventis Collaboration Agreement); provided that any action taken in connection with the Transaction shall not be deemed to be a violation of Section 20.16 of the Aventis Collaboration Agreement; and

(f) the Investor, upon written notice to the Company, so long as the Investor and Sanofi US are not then in breach of their representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 8.1 or 8.2, as applicable, could not be satisfied by the Closing Date, upon a breach of any covenant or agreement on the part of the Company set forth in this Agreement, or if any representation or warranty of the Company shall have been or become untrue, in each case such that any of the conditions set forth in Section 7.1, 7.2, 7.3 or 7.4, as applicable, could not be satisfied by the Closing Date.

10.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 10.1 hereof, (a) this Agreement (except for this Section 10.2 and Article XII (other than Section 12.13), and any definitions set forth in this Agreement and used in such sections) shall forthwith become void and have no effect, without any liability on the part of any

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3447

Samsung Bioepis Exhibit 1017, pg. 3447

party hereto or its Affiliates, and (b) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 10.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

11. Additional Covenants and Agreements.

11.1 Legending of Existing Shares. At the Closing, the Investor shall cause Aventis to deliver to the Company the certificate(s) representing 2,799,552 shares of Common Stock issued to Aventis, and the Company shall (or shall cause its transfer agent to) promptly cancel such certificate and issue to Aventis a replacement certificate representing 2,799,552 shares of Common Stock and containing the legends set forth in Section 5.10 hereof.

11.2 Amendment of Aventis Agreement. Effective as of the date of this Agreement, the Investor hereby acknowledges and agrees that it shall be bound by (and shall cause its Affiliates to comply with) the restrictions applicable to Sanofi US (as successor to Aventis) under Section 20.16 of the Aventis Collaboration Agreement, and the Investor, Sanofi US and the Company acknowledge and agree that for purposes of Section 19.5 of the Aventis Collaboration Agreement, references to "Aventis" in such section include the Investor and its other Affiliates. The Investor, Sanofi US and the Company agree that, subject to clause (c) below, effective as of the date of this Agreement:

(a) The first clause of Section 20.16 of the Aventis Collaboration Agreement is hereby amended and restated in its entirety to read:

"From and after the Effective Date until the later of (A) the fifth (5th) anniversary of the expiration or earlier termination of the Term and (B) the fifth (5th) anniversary of the expiration or earlier termination of the "Term" (as such term is defined in the License and Collaboration Agreement among the Company, sanofi-aventis Amérique du Nord and Aventis dated as of November 28, 2007), neither Aventis nor any of its Affiliates (for purposes of this Section 20.16, Aventis, together with such Affiliates, being referred to as the "Investor") shall:"

(b) Section 20.16(a) of the Aventis Collaboration Agreement is hereby amended and restated in its entirety to read:

"(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Capital Stock and/or Common Stock Equivalents, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Capital Stock and/or Common Stock Equivalents, if after giving effect to such acquisition (and assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by the Investor), the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act) more than the Standstill Limit; provided, however, that notwithstanding the provisions of this Section 20.16, if the number of shares constituting Shares of Then Outstanding Capital Stock is reduced or if

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3448

Samsung Bioepis Exhibit 1017, pg. 3448

the aggregate ownership of the Investor is increased as a result of a recapitalization of Regeneron, the Investor shall not be required to dispose of any of its holdings of Shares of Then Outstanding Capital Stock even though such action resulted in Investor's ownership totaling more than the Standstill Limit; as used in this Section 20.16(a):

(i) "Common Stock Equivalents" shall mean any options, warrants or other securities or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Class A Stock or Common Stock; and

(ii) "Standstill Limit" shall mean (i) from November 28, 2007 until December 31, 2011, the lesser of (A) twenty-one percent (21%) of the Shares of Then Outstanding Capital Stock, in the case of this clause (A) only, calculated on a fully diluted basis assuming the full conversion into, or exercise or exchange for, shares of Common Stock of all Common Stock Equivalents outstanding (as such Common Stock Equivalents outstanding are calculated from Regeneron's most recent Form 10-Q or Form 10-K, as applicable, filed with the SEC), and (B) twenty-five percent (25%) of the Shares of Then Outstanding Capital Stock, and (ii) from and after January 1, 2012, thirty percent (30%) of the Shares of Then Outstanding Capital Stock;"

(c) Notwithstanding the foregoing, if this Agreement is terminated in accordance with Section 10 hereof, the amendments to Section 20.16 of the Aventis Collaboration Agreement set forth above shall be of no further force or effect, and the provisions of Section 20.16 of the Aventis Collaboration Agreement in effect immediately prior to the execution and delivery of this Agreement shall again be in full force and effect.

11.3 Market Listing. From the date hereof through the Closing Date, Company shall use all reasonable efforts to (a) maintain the listing and trading of the Common Stock on The NASDAQ Global Market and (b) effect the listing of the Shares on The NASDAQ Global Market, including submitting a notice of listing of additional shares with respect to the Shares to The NASDAQ Stock Market LLC no later than fifteen (15) calendar days prior to the Closing Date.

11.4 Notification under the HSR Act. The parties shall, as soon as practicable, and, in any event, no later than ten (10) days after the date of this Agreement, file or cause to be filed with the Federal Trade Commission and the Department of Justice the notifications required to be filed under the HSR Act and the rules and regulations promulgated thereunder with respect to the transactions contemplated by this Agreement. The parties will use all reasonable efforts to respond on a timely basis to any requests for additional information made by either of such agencies.

11.5 Assistance and Cooperation. Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including using all reasonable efforts to accomplish the following: (a) taking all

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3449

Samsung Bioepis Exhibit 1017, pg. 3449

reasonable acts necessary to cause the conditions precedent set forth in Sections 7, 8 and 9 to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from The NASDAQ Stock Market LLC with respect to the LAS); (b) obtaining all necessary actions or non-actions, waivers, consents, approvals, orders and authorizations from Governmental Authorities and the making of all necessary registrations, declarations and filings (including registrations, declarations and filings with Governmental Authorities, if any) and taking all reasonable steps as may be necessary to avoid any suit, claim, action, investigation or proceeding by any Governmental Authority; (c) obtaining all necessary consents, approvals or waivers from Third Parties; and (d) defending any suits, claims, actions, investigations or proceedings, whether judicial or administrative, challenging this Agreement or the consummation of the transactions contemplated hereby, including seeking to have any stay or temporary restraining order entered by any court or other Governmental Authority vacated or reversed. In addition, each of the Company and the Investor will promptly take any and all steps necessary to obtain any consent or to vacate or lift any order, writ, judgment, injunction, decree, stipulation, determination or award entered by or with any Governmental Authority relating to antitrust matters that would have the effect of making any of the transactions contemplated by this Agreement illegal or otherwise prohibiting or materially delaying their consummation. Notwithstanding anything to the contrary in this Section 11.5, nothing in this Section 11.5 will require the Investor to dispose of or hold separate any portion of its business or assets if such action, in the reasonable business judgment of the Investor, would impair, or be reasonably expected to impair, in any significant manner (i) the benefits to the Investor of the transactions contemplated by this Agreement, the Discovery Agreement or the Collaboration Agreements or (ii) the business, financial condition, results of operations or prospects of the Investor and its subsidiaries, taken as a whole.

11.6 Effect of Waiver of Condition to Closing. In the event that, as of the Closing, the Investor waives the condition regarding a Material Adverse Effect set forth in Section 7.5 of this Agreement, the Investor shall be deemed to have waived any right of recourse against the Company for, and agreed not to sue the Company in respect of, any and all events or inaccuracies in any representations or warranties of the Company (a) that, as of the Closing, have caused or would reasonably be expected to cause such Material Adverse Effect and (b) of which the Investor had notice in writing from the Company immediately prior to the Closing.

12. Miscellaneous.

12.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. The parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

12.2 Waiver. Waiver by a party of a breach hereunder by the other party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such party. No waiver

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3450

Samsung Bioepis Exhibit 1017, pg. 3450

shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

12.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit D attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either party may change its address by giving notice to the other party in the manner provided above.

12.4 Entire Agreement. This Agreement and the Investor Agreement (once executed), contain the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

12.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the Investor and the Company.

12.6 Headings; Nouns and Pronouns; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

12.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

12.8 Assignment. Neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (a) the prior written

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3451

Samsung Bioepis Exhibit 1017, pg. 3451

consent of Company in the case of any assignment by the Investor or (b) the prior written consent of the Investor in the case of an assignment by the Company.

12.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

12.10 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

12.11 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

12.12 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either party.

12.13 Survival of Warranties. The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing for eighteen (18) months, except for (a) the representations and warranties set forth in Sections 4.1, 4.2, 4.4, 4.8, 4.15, 4.16, 4.17, 4.18, 5.1, 5.2, 5.5, 5.7, 5.8, 5.9 and 5.10, which shall survive forever and (b) the representation and warranty of the Investor and Sanofi US in Section 5.11, which shall not survive the Closing. The parties hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Investor as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

12.14 Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

12.15 Expenses. Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of the Transaction Agreements.

(Signature Page Follows)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3452

Samsung Bioepis Exhibit 1017, pg. 3452

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

SANOFI-AVENTIS AMÉRIQUE DU NORD

By: /s/ Jean-Luc Renard
Name: Jean-Luc Renard
Title: Authorized Signatory

By: /s/ Karen Linehan
Name: Karen Linehan
Title: Authorized Signatory

SANOFI-AVENTIS US LLC
(Solely for purposes of
Sections 5.11, 8.2, 8.3, 11.2 and 12.13)

By: /s/ Karen Linehan
Name: Karen Linehan
Title: Authorized Signatory

By: /s/ Robin White
Name: Robin White
Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard Schleifer
Name: Leonard S. Schleifer, M.D., Ph.D.
Title: President & CEO

Signature Page to Stock Purchase Agreement,

EXHIBIT A

FORM OF CROSS RECEIPT

CROSS RECEIPT

Regeneron Pharmaceuticals, Inc. hereby acknowledges receipt from sanofi-aventis Amérique du Nord on [_____], 2007 of US$312,000,000.00, representing the purchase price for 12,000,000 shares of Common Stock, par value $0.001 per share, of Regeneron Pharmaceuticals, Inc., pursuant to that certain Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amérique du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.

REGENERON PHARMACEUTICALS, INC.

By: _____
Name:
Title:

sanofi-aventis Amérique du Nord hereby acknowledges receipt from Regeneron Pharmaceuticals, Inc. on [_____], 2007 of 12,000,000 shares of Common Stock, par value $0.001 per share, of Regeneron Pharmaceuticals, Inc., delivered pursuant to that certain Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amérique du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.

SANOFI-AVENTIS AMÉRIQUE DU NORD

By: _____
Name:
Title:

By: _____
Name:
Title:

EXHIBIT B

FORM OF INVESTOR AGREEMENT

[See the Investor Agreement, dated as of December 20, 2007, filed as Exhibit 10.21]

EXHIBIT C

CONDUCT OF THE BUSINESS PENDING CLOSING

The Company may refinance its 5½% Convertible Senior Subordinated Notes due 2008.

The Company, in its sole discretion, shall be entitled to make equity-based or phantom equity incentive and other compensation awards, pursuant to equity-based or phantom equity incentive and other compensation plans in effect on the date of this Agreement.

EXHIBIT D

NOTICES

(a) If to the Investor or Sanofi US:

sanofi-aventis
174, avenue de France
75013 Paris
France
Attention: General Counsel

with a copy to:

Jones Day
222 East 41st Street
New York, New York 10017
Attention: Jere R. Thomson

(b) If to the Company:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
U.S.A.
Attention: President
Copy: General Counsel

with a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street, 31st Floor
Boston, MA 02108
Attention: Kent A. Coit

Exhibit 10.21

INVESTOR AGREEMENT

By and Among

SANOFI-AVENTIS,

SANOFI-AVENTIS US LLC,

AVENTIS PHARMACEUTICALS INC.,

SANOFI-AVENTIS AMÉRIQUE DU NORD

AND

REGENERON PHARMACEUTICALS, INC.

Dated as of December 20, 2007

TABLE OF CONTENTS

	Page
1. DEFINITIONS	1
2. REGISTRATION RIGHTS	7
2.1 Required Registration	7
2.2 Underwritten Required Registration Required; Priority in Underwritten Offering	9
2.3 Priority in Required Registration	9
2.4 Revocation of Required Registration	10
2.5 Effective Required Registrations	10
2.6 Continuous Effectiveness of Registration Statement	11
2.7 Obligations of the Company	11
2.8 Furnish Information	14
2.9 Expenses	14
2.10 Indemnification	14
2.11 SEC Reports	16
2.12 Assignment of Registration Rights	16
3. RESTRICTIONS ON BENEFICIAL OWNERSHIP	17
3.1 Standstill	17
3.2 Amendment to Aventis Collaboration Agreement	18
4. RESTRICTIONS ON DISPOSITIONS	18
4.1 Lock-Up	18
4.2 Limitations Following Lock-Up Term	19
4.3 Certain Tender Offers	20
4.4 Offering Lock-Up	20
5. VOTING AGREEMENT	20
5.1 Voting of Securities	20
5.2 Certain Extraordinary Matters	21
5.3 Quorum	21
6. TERMINATION OF CERTAIN RIGHTS AND OBLIGATIONS	22
6.1 Termination of Registration Rights	22
6.2 Termination of Standstill Agreement	22
6.3 Termination of Restrictions on Dispositions	23
6.4 Termination of Voting Agreement	23
6.5 Effect of Termination	23
7. MISCELLANEOUS	23
7.1 Governing Law; Submission to Jurisdiction	23
7.2 Waiver	23
7.3 Notices	24

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3459

Samsung Bioepis Exhibit 1017, pg. 3459

	Page
7.4 Entire Agreement	24
7.5 Amendments	24
7.6 Headings; Nouns and Pronouns; Section References	24
7.7 Severability	24
7.8 Assignment	25
7.9 Successors and Assigns	25
7.10 Counterparts	25
7.11 Third Party Beneficiaries	25
7.12 No Strict Construction	25
7.13 Remedies	25
7.14 Specific Performance	25
7.15 No Conflicting Agreements	25

Exhibit A – Form of Irrevocable Proxy

Exhibit B – Notices

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3460

Samsung Bioepis Exhibit 1017, pg. 3460

INVESTOR AGREEMENT

THIS INVESTOR AGREEMENT (this "Agreement") is made as of December 20, 2007, by and among sanofi-aventis, a company organized under the laws of France, with its principal headquarters at 174, avenue de France, 75013 Paris, France ("sanofi-aventis"), sanofi-aventis US LLC, a Delaware limited liability company indirectly wholly owned by sanofi-aventis ("Sanofi US") and the successor-in-interest to Aventis Pharmaceuticals Inc. ("Aventis") with respect to the Aventis Collaboration Agreement, with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 00807, Aventis, a Delaware corporation and an indirect wholly owned subsidiary of the Investor with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 00807, sanofi-aventis Amérique du Nord, a *société en nom collectif* organized under the laws of France wholly owned by sanofi-aventis with its principal headquarters at 174, avenue de France, 75013 Paris, France (the "Investor", and, together with sanofi-aventis, Sanofi US and Aventis, the "Purchaser Parties"), and Regeneron Pharmaceuticals, Inc. (the "Company"), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

WHEREAS, the Stock Purchase Agreement, dated as of November 28, 2007, by and among the Investor, sanofi-aventis US and the Company (the "Purchase Agreement") provides for the issuance and sale by the Company to the Investor, and the purchase by the Investor, of a number of shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), equal to the Share Amount (as defined in the Purchase Agreement) (the "Purchased Shares"); and

WHEREAS, as a condition to consummating the transactions contemplated by the Purchase Agreement, the Purchaser Parties and the Company have agreed upon certain rights and restrictions as set forth herein with respect to the Purchased Shares and other securities of the Company beneficially owned by the Purchaser Parties and their respective Affiliates, and it is a condition to the closing under the Purchase Agreement that this Agreement be executed and delivered by the Purchaser Parties and the Company.

NOW, THEREFORE, in consideration of the premises and mutual agreements hereinafter set forth, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Definitions. As used in this Agreement, the following terms shall have the following meanings:

(a) "Acquisition Proposal" shall have the meaning set forth in Section 3.1(c).

(b) "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent

(50%) of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

(c) "Agreement" shall have the meaning set forth in the Preamble to this Agreement, including all Exhibits attached hereto.

(d) "Aventis" shall have the meaning set forth in the Preamble to this Agreement.

(e) "Aventis Collaboration Agreement" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Sanofi US and the Company, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, and Section 11.2 of the Purchase Agreement, as the same may be further amended from time to time.

(f) "Aventis Stock Purchase Agreement" shall mean the Stock Purchase Agreement, dated as of September 5, 2003, by and between Aventis and the Company.

(g) "beneficial owner," "beneficially owns," "beneficial ownership" and terms of similar import used in this Agreement shall, with respect to a Person, have the meaning set forth in Rule 13d-3 under the Exchange Act (i) assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by such Person and (ii) determined without regard for the number of days in which such Person has the right to acquire such beneficial ownership.

(h) "Business Day" shall mean a day on which commercial banking institutions in New York, New York are open for business.

(i) "Change of Control" shall mean, with respect to the Company, any of the following events: (i) any Person is or becomes the beneficial owner (except that a Person shall be deemed to have beneficial ownership of all shares that any such Person has the right to acquire, whether such right which may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all Shares of Then Outstanding Common Stock; (ii) the Company consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into the Company, other than (A) a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3462

Samsung Bioepis Exhibit 1017, pg. 3462

(either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of a majority of the total voting power of all Shares of Then Outstanding Common Stock or (iii) the Company conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly owned Affiliate of the Company.

(j) "Class A Stock" shall mean the Class A Stock, par value $0.001 per share, of the Company.

(k) "Closing Date" shall have the meaning set forth in the Purchase Agreement.

(l) "Common Stock" shall have the meaning set forth in the Preamble to this Agreement.

(m) "Common Stock Equivalents" shall mean any options, warrants or other securities (including Class A Stock) or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Common Stock.

(n) "Company" shall have the meaning set forth in the Preamble to this Agreement.

(o) "Demand Request" shall have the meaning set forth in Section 2.1.

(p) "Disposition" or "Dispose of" shall mean any (i) offer, pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Class A Stock or Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (ii) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Class A Stock or Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

(q) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC promulgated thereunder.

(r) "Extraordinary Matter" shall have the meaning set forth in Section 5.2.

(s) "Filing Date" shall mean (i) with respect to any Registration Statement to be filed on Form S-1 (or any applicable successor form), ninety (90) days after receipt by the Company of a Demand Request for such Registration Statement and (ii) with respect to any Registration Statement to be filed on Form S-3 (or any applicable successor form), forty-five (45) days after receipt by the Company of a Demand Request for such Registration Statement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3463

Samsung Bioepis Exhibit 1017, pg. 3463

(t) "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.

(u) "Holders" shall mean (but, in each case, only for so long as such Person remains an Affiliate of sanofi-aventis) the Investor, Aventis and any Permitted Transferee thereof, if any, in accordance with Section 2.12.

(v) "Initiating Holder" shall have the meaning set forth in Section 2.2.

(w) "Interference" shall have the meaning set forth in Section 2.5.

(x) "Investor" shall have the meaning set forth in the Preamble to this Agreement.

(y) "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

(z) "Lock-Up Term" shall have the meaning set forth in Section 4.1.

(aa) "Modified Clause" shall have the meaning set forth in Section 7.7. (bb) "Offeror" shall have the meaning set forth in Section 3.1(c).

(cc) "Other Holders" shall mean any Person having rights to participate in a registration of the Company's securities.

(dd) "Permitted Transferee" shall mean a controlled Affiliate of sanofi-aventis that is wholly owned, directly or indirectly, by sanofi-aventis; it being understood that for purposes of this definition "wholly owned" shall mean an Affiliate in which sanofi-aventis owns, directly or indirectly, at least ninety-nine percent (99%) of the outstanding capital stock of such Affiliate.

(ee) "Person" shall mean any individual, partnership, firm, corporation, association, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

(ff) "Prospectus" shall mean the prospectus forming a part of any Registration Statement, as supplemented by any and all prospectus supplements and as amended by any and all amendments (including post-effective amendments) and including all material incorporated by reference or explicitly deemed to be incorporated by reference in such prospectus.

(gg) "Purchase Agreement" shall have the meaning set forth in the Preamble to this Agreement, and shall include all Exhibits attached thereto.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3464

Samsung Bioepis Exhibit 1017, pg. 3464

(hh) "Purchased Shares" shall have the meaning set forth in the Preamble to this Agreement, and shall be adjusted for (i) any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Purchased Shares.

(ii) "Purchaser Parties" shall have the meaning set forth in the Preamble to this Agreement.

(jj) "registers," "registered," and "registration" refer to a registration effected by preparing and filing a Registration Statement or similar document in compliance with the Securities Act, and the declaration or ordering of effectiveness of such Registration Statement or document by the SEC.

(kk) "Registrable Securities" shall mean (i) the Purchased Shares and any shares of Common Stock owned of record by Aventis as of the date of this Agreement, together with any shares of Common Stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (i) of this definition, excluding in all cases, however, (A) any Registrable Securities if and after they have been transferred to a Permitted Transferee in a transaction in connection with which registration rights granted hereunder are not assigned, (B) any Registrable Securities sold to or through a broker or dealer or underwriter in a public distribution or a public securities transaction or (C) Registrable Securities eligible for resale pursuant to Rule 144(k) under the Securities Act.

(ll) "Registration Expenses" shall mean all expenses incurred by the Company in connection with any Required Registration pursuant to Section 2.1 or the Company's compliance with Section 2.7 (excluding clauses (m), (n) and (r) thereof), including, without limitation, all registration and filing fees, fees and expenses of compliance with securities or blue sky Laws (including reasonable fees and disbursements of counsel in connection with blue sky qualifications of any Registrable Securities), expenses of printing (i) certificates for any Registrable Securities in a form eligible for deposit with the Depository Trust Company or (ii) Prospectuses if the printing of Prospectuses is requested by Holders, messenger and delivery expenses, fees and disbursements of counsel for the Company and its independent certified public accountants (including the expenses of any management review, cold comfort letters or any special audits required by or incident to such performance and compliance), Securities Act liability insurance (if the Company elects to obtain such insurance), the reasonable fees and expenses of any special experts retained by the Company in connection with such registration, fees and expenses of other Persons retained by the Company and the reasonable fees and expenses of one (1) counsel for the Holders of Registrable Securities in each Required Registration, selected by the Holders of a majority of the Registrable Securities to be included in such Required Registration. In addition, the Company will pay its internal expenses (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Purchased Shares to be registered on each securities exchange,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3465

Samsung Bioepis Exhibit 1017, pg. 3465

if any, on which equity securities issued by the Company are then listed or the quotation of such securities on any national securities exchange on which equity securities issued by the Company are then quoted.

(mm) "Registration Rights Term" shall have the meaning set forth in Section 2.1.

(nn) "Registration Statement" shall mean any registration statement of the Company under the Securities Act that covers any of the Registrable Securities pursuant to the provisions of this Agreement, including the related Prospectus, all amendments and supplements to such registration statement (including post-effective amendments), and all exhibits and all materials incorporated by reference or explicitly deemed to be incorporated by reference in such Registration Statement.

(oo) "Required Period" with respect to a Required Registration shall mean the earlier of (i) the date on which all Registrable Securities covered by such Required Registration are sold pursuant thereto and (ii) one-hundred twenty (120) days following the first day of effectiveness of the Registration Statement for such Required Registration, in each case subject to extension as set forth herein; provided, however, that in no event will the Required Period expire prior to the expiration of the applicable period referred to in Section 4(3) of the Securities Act and Rule 174 promulgated thereunder.

(pp) "Required Registration" shall have the meaning set forth in Section 2.1.

(qq) "Sanofi License and Collaboration Agreement" shall mean that certain License and Collaboration Agreement between the Company, the Investor and Aventis dated as of November 28, 2007, as the same may be amended from time to time.

(rr) "sanofi-aventis" shall have the meaning set forth in the Preamble to this Agreement.

(ss) "Sanofi US" shall have the meaning set forth in the Preamble to this Agreement.

(tt) "SEC" shall mean the United States Securities and Exchange Commission.

(uu) "Securities Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the SEC promulgated thereunder.

(vv) "Selling Expenses" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities pursuant to this Agreement.

(ww) "Shares of Then Outstanding Common Stock" shall mean, at any time, the issued and outstanding shares of Class A Stock and Common Stock at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend, or reclassification of Class A Stock or Common Stock distributable, on a pro rata basis, to all holders of Class A Stock and Common Stock, as applicable.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3466

Samsung Bioepis Exhibit 1017, pg. 3466

(xx) "Standstill Limit" shall mean (i) from the Closing Date until the fourth (4th) anniversary of the Closing Date, the lesser of (A) twenty-one percent (21%) of the Shares of Then Outstanding Common Stock, in the case of this clause (A) only, calculated on a fully diluted basis assuming the full conversion into, or exercise or exchange for, shares of Common Stock of all Common Stock Equivalents outstanding (as such Common Stock Equivalents outstanding are calculated from the Company's most recent Form 10-Q or Form 10-K, as applicable, filed with the SEC), and (B) twenty-five percent (25%) of the Shares of Then Outstanding Common Stock, and (ii) from the fourth (4th) anniversary of the Closing Date until the expiration of the Standstill Term, thirty percent (30%) of the Shares of Then Outstanding Common Stock.

(yy) "Standstill Parties" shall have the meaning set forth in Section 3.1. (zz) "Standstill Term" shall have the meaning set forth in Section 3.1.

(aaa) "Third Party" shall mean any Person other than the Purchaser Parties, the Company or any of their respective Affiliates.

(bbb) "Underwritten Registration" or "Underwritten Offering" shall mean a registration in which Registrable Securities are sold to an underwriter for reoffering to the public.

(ccc) "Violation" shall have the meaning set forth in Section 2.10(a).

2. Registration Rights.

2.1 Required Registration. If, at any time after the expiration of the Lock-Up Term but no later than the tenth (10th) anniversary of such expiration (the "Registration Rights Term"), the Company receives from any Holder or Holders a written request or requests (each, a "Demand Request") that the Company file a Registration Statement under the Securities Act to effect the registration (a "Required Registration") of Registrable Securities, the Company shall use all reasonable efforts to file a Registration Statement covering such Holders' Registrable Securities as soon as practicable (and by the applicable Filing Date) and shall use all reasonable efforts to, as soon as practicable thereafter, effect the registration of the Registrable Securities to permit or facilitate the sale and distribution in an Underwritten Offering of all or such portion of such Holder's or Holders' Registrable Securities as are specified in such Demand Request, subject however, to the conditions and limitations set forth herein; provided, however, that the Company shall not be obligated to effect any registration of Registrable Securities upon receipt of a Demand Request pursuant to this Section 2.1 if:

(i) the Company has already completed three (3) Required Registrations;

(ii) (A) in the event that the market value of all Registrable Securities outstanding is equal to or greater than $50,000,000, the market value of the Registrable Securities proposed to be included in the registration, based on the average closing price during the ten (10) consecutive trading days period prior to the making of the Demand Request, is less than $50,000,000 or (B) in the event that the market value of all Registrable Securities outstanding is less than

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3467

Samsung Bioepis Exhibit 1017, pg. 3467

$50,000,000, (i) less than all such Registrable Securities are proposed to be included in the registration, or (ii) the market value of all such Registrable Securities is less than $25,000,000;

(iii) the Company shall furnish to the Holders a certificate signed by an authorized officer of the Company stating that (A) within ninety (90) days of receipt of the Demand Request under this Section 2.1, the Company shall file a registration statement for the public offering of securities for the account of the Company (other than a registration of securities (x) issuable pursuant to an employee stock option, stock purchase or similar plan, (y) issuable pursuant to a merger, exchange offer or a transaction of the type specified in Rule 145(a) under the Securities Act or (z) in which the only securities being registered are securities issuable upon conversion of debt securities which are also being registered), or (B) the Company is engaged in a material transaction or has an undisclosed material corporate development, in either case, which would be required to be disclosed in the Registration Statement, and in the good faith judgment of the Company's Board of Directors, such disclosure would be seriously detrimental to the Company and its stockholders at such time (in which case, the Company shall disclose the matter as promptly as reasonably practicable and thereafter file the Registration Statement, and each Holder agrees not to disclose any information about such material transaction to Third Parties until such disclosure has occurred or such information has entered the public domain other than through breach of this provision by such Holder), provided, however, that the Company shall have the right to only defer the filing of the Registration Statement pursuant to this subsection once in any twelve (12) month period and, such deferral may not exceed a period of more than one-hundred twenty (120) days after receipt of a Demand Request;

(iv) the Company has, within the twelve (12) month period preceding the date of the Demand Request, already effected one (1) Required Registration for any Holder pursuant to this Section 2.1; or

(v) at any time during the period between the Company's receipt of the Demand Request and the completion of the Required Registration, any Holder is in breach of or has failed to cause its Affiliates to comply with the obligations and restrictions of Sections 3, 4 or 5 of this Agreement, and such breach or failure is ongoing and has not been remedied; it being understood that (A) a one-time, inadvertent and de minimis breach of Section 4 shall not be deemed to be a breach of the obligations and restrictions under Section 4 for purposes of this Section 2.1(v) and (B) a de minimis breach of Section 3.1(a) hereof, or an inadvertent breach of Section 3.1(g) hereof arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 3.1, shall not be deemed to be a breach of the obligations and restrictions under Section 3.1 for purposes of this Section 2.1(v).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3468

Samsung Bioepis Exhibit 1017, pg. 3468

2.2 Underwritten Required Registration Required; Priority in Underwritten Offering. The underwriter for any Underwritten Offering requested pursuant to Section 2.1 shall be selected by a majority in interest of the Holders initiating the Required Registration hereunder (such Holder(s) initiating the registration request, the "Initiating Holders") and shall be acceptable to the Company. The right of any Holder to include its Registrable Securities in the Underwritten Offering shall be conditioned upon such Holder's participation in such Underwritten Offering and the inclusion of such Holder's Registrable Securities to the extent provided herein. All Holders requesting the inclusion of their Registrable Securities in such Underwritten Offering shall (together with the Company as provided in Section 2.7(h)) enter into an underwriting agreement in customary form with the underwriter or underwriters selected for such Underwritten Offering. Notwithstanding any other provision of this Section 2, if the managing underwriter for the Underwritten Offering determines in good faith that marketing factors require a limitation of the number of shares of Registrable Securities to be included in such Underwritten Offering, then the Company shall so advise all Holders which requested inclusion of their Registrable Securities in such Underwritten Offering, and the number of shares of Registrable Securities that may be included in such Underwritten Offering shall be allocated among the Holders in proportion (as nearly as practicable) to the amount of Registrable Securities of the Company owned by each Holder; provided, however, that the number of shares of Registrable Securities to be included in such Underwritten Offering shall not be reduced unless all other securities are first entirely excluded from such Underwritten Offering. In the event the Company advises the Holders of its intent to decrease the total number of Registrable Securities that may be included by the Holders in such Required Registration such that the number of Registrable Securities included in such Required Registration would be less than seventy-five percent (75%) of all Registrable Securities which the Holders requested be included in such Required Registration, then Holders representing a majority of the Registrable Securities requested to be included in such Required Registration will have the right to withdraw, on behalf of all Holders of all Registrable Securities requested to be so included, such Required Registration, in which case, such Required Registration will not count as a Required Registration for the purposes of Section 2.1(i), and the Company shall bear all Registration Expenses in connection therewith; provided, that, the right to withdraw a registration and have it not count as a Required Registration may only be exercised once by the Holders (taken collectively).

2.3 Priority in Required Registration. With respect to any Required Registration of Registrable Securities requested pursuant to Section 2.1, the Company may also (i) propose to sell shares of Common Stock on its own behalf and (ii) provide written notice of such Required Registration to Other Holders and permit all such Other Holders who request to be included in the Required Registration to include any or all Company securities held by such Other Holders in such Required Registration on the same terms and conditions as the Registrable Securities. Notwithstanding the foregoing, if the managing underwriter or underwriters of the Underwritten Offering to which any Required Registration relates advise the Company and the Holders of Registrable Securities that, in its good faith determination, the total amount of securities that such Holders, Other Holders, and the Company intend to include in such Required Registration is in an amount in the aggregate which would adversely affect the success of such Underwritten Offering, then such Required Registration shall include (i) first, all Registrable Securities of the Holders allocated, if the amount is less than all the Registrable Securities requested to be sold, *pro rata* on the basis of the total number of Registrable Securities held by such Holders; and (ii) second, as many other securities proposed to be included in the Required Registration by the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3469

Samsung Bioepis Exhibit 1017, pg. 3469

Company and any Other Holders, allocated *pro rata* among the Company and such Other Holders, on the basis of the amount of securities requested to be included therein by the Company and each such Other Holder so that the total amount of securities to be included in such Underwritten Offering is the full amount that, in the written opinion of such managing underwriter, can be sold without materially and adversely affecting the success of such Underwritten Offering.

2.4 Revocation of Required Registration. With respect to one (1) Required Registration only, the Holders of at least a majority of the Registrable Securities to be included in a Registration Statement with respect to such Required Registration may, at any time prior to the effective date of such Registration Statement, on behalf of all Holders of all Registrable Securities requested to be included therein, revoke the request to have Registrable Securities included therein and revoke the request for such Required Registration by providing a written notice to the Company, in which case such Required Registration that has been revoked will be deemed not to have been effected and will not count as a Required Registration for purposes of Section 2.1(i) if, and only if, the Holders of Registrable Securities which had requested inclusion of Registrable Securities in such Required Registration promptly reimburse the Company for all Registration Expenses incurred by the Company in connection with such Required Registration. Notwithstanding the foregoing sentence, the parties agree and acknowledge that the Holders may revoke any Required Registration (without any obligation to reimburse the Company for Registration Expenses incurred in connection therewith) if such revocation is based on (i) a material adverse change in circumstances with respect to the Company and its subsidiaries, taken as a whole, caused by an act or failure to act by the Company or any of its subsidiaries and not known to any Holder at the time the Required Registration was first made or (ii) the Company's failure to comply in any material respect with its obligations hereunder, and any such revocation based on an event described in (i) or (ii) above shall be exercisable at any time and shall not be counted as the one (1) revocation of a Required Registration permitted by the first sentence of this Section 2.4.

2.5 Effective Required Registrations. A Required Registration will not be deemed to be effected for purposes of Section 2.1(i) if the Registration Statement for such Required Registration has not been declared effective by the SEC or become effective in accordance with the Securities Act and the rules and regulations thereunder and kept effective for the Required Period. In addition, if after such Registration Statement has been declared or becomes effective, (i) the offering of Registrable Securities pursuant to such Registration Statement is interfered with by any stop order, injunction, or other order or requirement of the SEC or other governmental agency or court such that the continued offer and sale of Registrable Securities being offered pursuant to such Registration Statement would violate applicable Law and such stop order, injunction or other order or requirement of the SEC or other governmental agency or court does not result from any act or omission of any Holder whose Registrable Securities are registered pursuant to such Registration Statement (an "Interference") and (ii) any such Interference is not cured within sixty (60) days thereof, such Required Registration will be deemed not to have been effected and will not count as a Required Registration. In the event such Interference occurs and is cured, the Required Period relating to such Registration Statement will be extended by the number of days of such Interference, including the date such Interference is cured.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3470

Samsung Bioepis Exhibit 1017, pg. 3470

2.6 Continuous Effectiveness of Registration Statement. The Company will use all reasonable efforts to cause each Registration Statement filed pursuant to this Section 2 to be declared effective by the SEC or to become effective under the Securities Act as promptly as practicable and to keep each such Registration Statement that has been declared or becomes effective continuously effective for the Required Period.

2.7 Obligations of the Company. Whenever required under Section 2.1 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a Registration Statement with respect to such Registrable Securities sought to be included therein; provided that at least five (5) Business Days prior to filing any Registration Statement or Prospectus or any amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and the managing underwriter copies of all such documents proposed to be filed, and any such Holder shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder or the managing underwriter with respect to such information prior to filing any such Registration Statement or amendment;

(b) prepare and file with the SEC such amendments and post-effective amendments to any Registration Statement and any Prospectus used in connection therewith as may be necessary to keep such Registration Statement effective for the Required Period, and cause the Prospectus to be supplemented by any required prospectus supplement, and as so supplemented to be filed pursuant to Rule 424 under the Securities Act, to comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement for the Required Period; provided that at least five (5) Business Days prior to filing any such amendments and post effective amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and the managing underwriter copies of all such documents proposed to be filed, and any such Holder or managing underwriter shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder and the managing underwriter with respect to such information prior to filing any such Registration Statement or amendment;

(c) furnish to the Holders of Registrable Securities covered by such Registration Statement and the managing underwriter such numbers of copies of such Registration Statement, each amendment and supplement thereto, the Prospectus included in such Registration Statement (including each preliminary prospectus or free writing prospectus) in conformity with the requirements of the Securities Act, and such other documents as they may reasonably request in order to facilitate the disposition of Registrable Securities owned by them;

(d) notify the Holders of Registrable Securities covered by such Registration Statement, promptly after the Company shall receive notice thereof, of the time when such

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3471

Samsung Bioepis Exhibit 1017, pg. 3471

Registration Statement becomes or is declared effective or when any amendment or supplement or any Prospectus forming a part of such Registration Statement has been filed;

(e) notify the Holders of Registrable Securities covered by such Registration Statement promptly of any request by the SEC for the amending or supplementing of such Registration Statement or Prospectus or for additional information and promptly deliver to such Holders copies of any comments received from the SEC;

(f) notify the Holders promptly of any stop order suspending the effectiveness of such Registration Statement or Prospectus or the initiation of any proceedings for that purpose, and use all reasonable efforts to obtain the withdrawal of any such order or the termination of such proceedings;

(g) use all reasonable efforts to register and qualify the Registrable Securities covered by such Registration Statement under such other securities or blue sky Laws of such jurisdictions as shall be reasonably requested by the Holders, use all reasonable efforts to keep each such registration or qualification effective, including through new filings, or amendments or renewals, during the Required Period, and notify the Holders of Registrable Securities covered by such Registration Statement of the receipt of any written notification with respect to any suspension of any such qualification; provided, however, that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions;

(h) enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter of the Underwritten Offering pursuant to which such Registrable Securities are being offered;

(i) use all reasonable efforts to obtain: (A) at the time of effectiveness of the Registration Statement covering such Registrable Securities, a "cold comfort letter" from the Company's independent certified public accountants covering such matters of the type customarily covered by "cold comfort letters" as the underwriters may reasonably request; and (B) at the time of any underwritten sale pursuant to such Registration Statement, a "bring-down comfort letter," dated as of the date of such sale, from the Company's independent certified public accountants covering such matters of the type customarily covered by "bring-down comfort letters" as the underwriters may reasonably request.

(j) promptly notify each Holder of Registrable Securities covered by such Registration Statement at any time when a Prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which the Prospectus included in such Registration Statement or any offering memorandum or other offering document includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing, and promptly prepare a supplement or amendment to such Prospectus or file any other required document so that, as thereafter delivered to the purchasers of such Registrable Securities, such Prospectus will not contain an untrue statement of material fact or omit to state any fact necessary to make the statements therein not misleading;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3472

Samsung Bioepis Exhibit 1017, pg. 3472

(k) permit any Holder of Registrable Securities covered by such Registration Statement, which Holder in its reasonable judgment could reasonably be deemed to be an underwriter with respect to the Underwritten Offering pursuant to which such Registrable Securities are being offered, or to be a controlling Person of the Company, to reasonably participate in the preparation of such Registration Statement and to require the insertion therein of information to the extent concerning such Holder, furnished to the Company in writing, which in the reasonable judgment of such Holder and its counsel should be included;

(l) in connection with any Underwritten Offering, use all reasonable efforts to obtain an opinion or opinions addressed to the underwriter or underwriters in customary form and scope from counsel for the Company;

(m) upon reasonable notice and during normal business hours, subject to the Company receiving customary confidentiality undertakings or agreements from any Holder of Registrable Securities covered by such Registration Statement or other person obtaining access to Company records, documents, properties or other information pursuant to this subsection (m), make available for inspection by a representative of such Holder and any underwriter participating in any disposition of such Registrable Securities and any attorneys or accountants retained by any such Holder or underwriter, relevant financial and other records, pertinent corporate documents and properties of the Company, and use all reasonable efforts to cause the officers, directors and employees of the Company to supply all information reasonably requested by any such representative, underwriter, attorneys or accountants in connection with the Registration Statement;

(n) with respect to one (1) Required Registration which includes Registrable Securities the market value of which is at least one hundred million United States dollars ($100,000,000), participate, to the extent requested by the managing underwriter, in efforts extending for no more than five (5) days scheduled by such managing underwriter and reasonably acceptable to the Company's senior management, to sell the Registrable Securities being offered pursuant to such Required Registration (including participating during such period in customary "roadshow" meetings with prospective investors);

(o) use all reasonable efforts to comply with all applicable rules and regulations of the SEC relating to such registration and make generally available to its security holders earning statements satisfying the provisions of Section 11(a) of the Securities Act, provided that the Company will be deemed to have complied with this Section 2.7(o) with respect to such earning statements if it has satisfied the provisions of Rule 158;

(p) if requested by the managing underwriter or any selling Holder, promptly incorporate in a prospectus supplement or post-effective amendment such information as the managing underwriter or any selling Holder reasonably requests to be included therein, with respect to the Registrable Securities being sold by such selling Holder, including, without limitation, the purchase price being paid therefor by the underwriters and with respect to any other terms of the Underwritten Offering of Registrable Securities to be sold in such offering, and promptly make all required filings of such prospectus supplement or post-effective amendment;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3473

Samsung Bioepis Exhibit 1017, pg. 3473

(q) cause the Registrable Securities covered by such Registration Statement to be listed on each securities exchange, if any, on which equity securities issued by the Company are then listed; and

(r) reasonably cooperate with each selling Holder and each underwriter participating in the disposition of such Registrable Securities and their respective counsel in connection with filings required to be made with the Financial Industry Regulatory Authority, Inc., if any.

2.8 Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself and the Registrable Securities held by it as shall be reasonably necessary to effect the registration of such Holder's Registrable Securities.

2.9 Expenses. Except as specifically provided herein, all Registration Expenses shall be borne by the Company. All Selling Expenses incurred in connection with any registration hereunder shall be borne by the Holders of Registrable Securities covered by a Registration Statement, pro rata on the basis of the number of Registrable Securities registered on their behalf in such Registration Statement.

2.10 Indemnification. In the event any Registrable Securities are included in a Registration Statement under this Agreement:

(a) The Company shall indemnify and hold harmless each Holder including Registrable Securities in any such Registration Statement, any underwriter (as defined in the Securities Act) for such Holder and each Person, if any, who controls such Holder or underwriter within the meaning of Section 15 of the Securities Act or Section 20 of Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, against any and all losses, claims, damages or liabilities (joint or several) to which they may become subject under any securities Laws including, without limitation, the Securities Act, the Exchange Act, or any other statute or common law of the United States or any other country or political subdivision thereof, or otherwise, including the amount paid in settlement of any litigation commenced or threatened (including any amounts paid pursuant to or in settlement of claims made under the indemnification or contribution provisions of any underwriting or similar agreement entered into by such Holder in connection with any offering or sale of securities covered by this Agreement), and shall promptly reimburse them, as and when incurred, for any legal or other expenses incurred by them in connection with investigating any claims and defending any actions, insofar as any such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (each, a "Violation"): (i) any untrue statement or alleged untrue statement of a material fact contained in or incorporated by reference into such Registration Statement, including any preliminary prospectus or final prospectus contained therein or any free writing prospectus or any amendments or supplements thereto, or in any offering memorandum or other offering document relating to the offering and sale of such securities or (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; provided, however, the Company shall not be liable in any such case for any such loss, claim,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3474

Samsung Bioepis Exhibit 1017, pg. 3474

damage, liability or action to the extent that it (A) arises out of or is based upon a Violation which occurs solely in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (B) is caused by such Holder's disposition of Registrable Shares during any period during which such Holder is obligated to discontinue any disposition of Registrable Shares as a result of any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities.

(b) Each Holder including Registrable Securities in a registration statement shall indemnify and hold harmless the Company, each of its directors, each of its officers who has signed the registration statement, each Person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, any underwriter, any other Holder selling securities in such registration statement and any controlling Person of any such underwriter or other Holder, against any losses, claims, damages or liabilities (joint or several) to which any of the foregoing Persons may become subject, under liabilities (or actions in respect thereto) which arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation: (i) arises out of or is based upon a Violation which occurs solely in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (ii) is caused by such Holder's disposition of Registrable Shares during any period during which such Holder is obligated to discontinue any disposition of Registrable Shares as a result of any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities. Each such Holder shall pay, as incurred, any legal or other expenses reasonably incurred by any Person intended to be indemnified pursuant to this Section 2.10(b), in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the indemnity agreement contained in this Section 2.10(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without consent of the Holder, which consent shall not be unreasonably withheld.

(c) Promptly after receipt by an indemnified party under this Section 2.10 of notice of the commencement of any action (including any action by a Governmental Authority), such indemnified party shall, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.10, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party shall have the right to retain its own counsel, with the reasonable fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.10, but the omission so to deliver written notice to the indemnifying party shall not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.10.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3475

Samsung Bioepis Exhibit 1017, pg. 3475

(d) In order to provide for just and equitable contribution to joint liability in any case in which a claim for indemnification is made pursuant to this Section 2.10 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 2.10 provided for indemnification in such case, the Company and each Holder of Registrable Securities shall contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in proportion to the relative fault of the Company, on the one hand, and such Holder, severally, on the other hand; provided, however, that in any such case, no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; provided further, however, that in no event shall any contribution under this Section 2.10(d) on the part of any Holder exceed the net proceeds received by such Holder from the sale of Registrable Securities giving rise to such contribution obligation.

(e) The obligations of the Company and the Holders under this Section 2.10 shall survive the completion of any offering of Registrable Securities in a registration statement under this Agreement and otherwise.

2.11 SEC Reports. With a view to making available to the Holders the benefits of Rule 144 under the Securities Act and any other rule or regulation of the SEC that may at any time permit a Holder to sell Registrable Securities of the Company to the public without registration, the Company agrees to at any time that it is a reporting company under Section 13 or 15(d) of the Exchange Act:

(a) file with the SEC in a timely manner all reports and other documents required of the Company under the Exchange Act; and

(b) furnish to any Holder, so long as such Holder owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of the Exchange Act, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC (exclusive of Rule 144A) which permits the selling of any Registrable Securities without registration.

2.12 Assignment of Registration Rights. The rights to cause the Company to register any Registrable Securities pursuant to this Agreement may be assigned in whole or in part (but only with all restrictions and obligations set forth in this Agreement) by a Holder to a Permitted Transferee which acquires Registrable Securities from such Holder; provided, however, (a) such Holder shall, within five (5) days prior to such transfer, furnish to the Company written notice of the name and address of such Permitted Transferee, details of its status as a Permitted Transferee and details of the Registrable Securities with respect to which such registration rights are being assigned, (b) the Permitted Transferee, prior to or simultaneously with such transfer or assignment, shall agree in writing to be subject to and bound by all restrictions and obligations set forth in this Agreement, (c) the Purchaser Parties shall continue to be bound by all restrictions

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3476

Samsung Bioepis Exhibit 1017, pg. 3476

and obligations set forth in this Agreement and (d) such transfer or assignment shall be effective only if immediately following such transfer or assignment the further disposition of such Registrable Securities by the Permitted Transferee is restricted under the Securities Act and other applicable securities Law.

3. Restrictions on Beneficial Ownership.

3.1 Standstill. During the period (such period, the "Standstill Term") from and after the date of this Agreement until the later of (A) the fifth (5th) anniversary of the expiration or earlier termination of the "Term" (as such term is defined in the Aventis Collaboration Agreement) and (B) the fifth (5th) anniversary of the expiration or earlier termination of the "Term" (as such term is defined in the Sanofi License and Collaboration Agreement), neither the Purchaser Parties nor any of their respective Affiliates (collectively, the "Standstill Parties") shall (and the Purchaser Parties shall cause their respective Affiliates not to), except as expressly approved or invited in writing by the Company:

(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Common Stock and/or Common Stock Equivalents, if after giving effect to such acquisition, the Standstill Parties would beneficially own more than the Standstill Limit; provided, however, that notwithstanding the provisions of this Section 3.1(a), if the number of shares constituting Shares of Then Outstanding Common Stock is reduced or if the aggregate ownership of the Standstill Parties is increased as a result of a repurchase of Shares of Then Outstanding Common Stock, stock split, stock dividend or a recapitalization of the Company, the Standstill Parties shall not be required to dispose of any of their holdings of Shares of Then Outstanding Common Stock even though such action resulted in the Standstill Parties' beneficial ownership totaling more than the Standstill Limit;

(b) directly or indirectly, seek to have called any meeting of the stockholders of the Company, propose or nominate for election to the Company's Board of Directors any person whose nomination has not been approved by a majority of the Company's Board of Directors or cause to be voted in favor of such person for election to the Company's Board of Directors any Shares of Then Outstanding Common Stock;

(c) directly or indirectly, encourage or support a tender, exchange or other offer or proposal by any other Person or group (an "Offeror") the consummation of which would result in a Change of Control of the Company (an "Acquisition Proposal");

(d) directly or indirectly, solicit proxies or consents or become a participant in a solicitation (as such terms are defined in Regulation 14A under the Exchange Act) in opposition to the recommendation of a majority of the Company's Board of Directors with respect to any matter, or seek to advise or influence any Person, with respect to voting of any Shares of Then Outstanding Common Stock of the Company;

(e) deposit any Shares of Then Outstanding Common Stock in a voting trust or subject any Shares of Then Outstanding Common Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Common Stock;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3477

Samsung Bioepis Exhibit 1017, pg. 3477

(f) act in concert with any Third Party to take any action in clauses (a) through (e) above, or form, join or in any way participate in a "partnership, limited partnership, syndicate, or other group" within the meaning of Section 13(d)(3) of the Exchange Act.

(g) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in (a) through (e) above; or

(h) request or propose in writing to the Company's Board of Directors, any member(s) thereof or any officer of the Company that the Company amend, waive, or consider the amendment or waiver of, any provisions set forth in this Section 3.1;

provided, however, that the mere voting in accordance with Section 5 hereof of any voting securities of the Company held by the Purchaser Parties or their Affiliates shall not constitute a violation of any of clauses (a) through (h) above.

3.2 Amendment to Aventis Collaboration Agreement. Sections 3.1 and 6.2 of this Agreement shall, effective as of the date of this Agreement, supersede and replace Sections 20.16 and 20.17 of the Aventis Collaboration Agreement. The foregoing sentence shall not impair the rights of the Company or constitute a waiver by the Company of any breach or default by Aventis, Sanofi US or any of their Affiliates under Sections 20.16 and 20.17 of the Aventis Collaboration Agreement. sanofi-aventis, the Investor, Sanofi US and the Company agree that Section 19.5 of the Aventis Collaboration Agreement is hereby amended and restated in its entirety to read:

"Notwithstanding anything to the contrary herein, Regeneron will have the unilateral right to terminate this Agreement in its entirety, upon written notice to Aventis, if any of the Standstill Parties (as defined in the Investor Agreement, dated as of [_____], 2007 (the "Investor Agreement"), by and among sanofi-aventis, sanofi-aventis US LLC, Aventis, sanofi-aventis Amérique du Nord and Regeneron) shall have breached Section 3.1 of the Investor Agreement. For the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of a de minimis breach of Section 3.1(a) of the Investor Agreement or an inadvertent breach of Section 3.1(g) of the Investor Agreement arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 3.1 of the Investor Agreement."

4. Restrictions on Dispositions.

4.1 Lock-Up. From and after the date of this Agreement and until the earlier of (i) the fifth (5th) anniversary of the date of this Agreement and (ii) the expiration, or earlier valid termination by Aventis in its entirety pursuant to Section 19.3 or 19.4 thereof, of the Sanofi License and Collaboration Agreement (the "Lock-Up Term"), without the prior approval of a majority of the Company's Board of Directors, the Purchaser Parties shall not, and shall cause their respective Affiliates not to, Dispose of (x) any of the Purchased Shares or any shares of Common Stock beneficially owned by any Standstill Party as of the date of this Agreement, together with any shares of Common Stock issued in respect thereof as a result of any stock split,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3478

Samsung Bioepis Exhibit 1017, pg. 3478

stock dividend, share exchange, merger, consolidation or similar recapitalization, and (y) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (x) of this sentence; provided, however, that the foregoing shall not prohibit the Investor or Aventis from (A) transferring Registrable Securities to a Permitted Transferee in accordance with and subject to the terms of Section 2.12, or (B) Disposing of any Shares of Then Outstanding Common Stock as they may hold from time to time in order to reduce the beneficial ownership of the Standstill Parties to 19.9% of the Shares of Then Outstanding Common Stock, provided that any such Disposition referred to in this clause (B), whether occurring before or after the expiration of the Lock-Up Term, shall be subject to the restrictions and requirements set forth in paragraphs (a), (b) and (c) of Section 4.2.

4.2 Limitations Following Lock-Up Term. The Purchaser Parties agree that, except for any transfer of Registrable Securities by the Investor or Aventis to a Permitted Transferee in accordance with and subject to the terms of Sections 2.12 and 4.1, they shall not, and shall cause their respective Affiliates not to, Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents at any time after the expiration of the Lock-Up Term except (i) pursuant to a registered underwritten public offering in accordance with Section 2, (ii) pursuant to Rule 144 under the Securities Act or (iii) pursuant to privately negotiated sales in transactions exempt from the registration requirements under the Securities Act; provided, however, that:

(a) In any Underwritten Offering in accordance with Section 2, the Holders whose Registrable Securities are included in such Underwritten Offering shall request that the underwriter for such Underwritten Offering, and shall require that the underwriter for such Underwritten Offering shall agree in writing to, use all reasonable efforts to make as broad a distribution as reasonably practical and to prevent any Person, or Affiliates of such Person, from purchasing in such offering Registrable Securities which would constitute, or result in such Person, together with such Person's Affiliates, having beneficial ownership of, five percent (5%) or more of the total shares of Common Stock then outstanding.

(b) The Purchaser Parties shall not (and shall cause their respective Affiliates not to), without the prior approval of a majority of the Company's Board of Directors, Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents if such Disposition, together with any Disposition(s) by any Standstill Parties during the immediately preceding three (3) months, would exceed one million (1,000,000) Shares of Then Outstanding Common Stock of the Company (assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents Disposed of by the Standstill Parties): provided, however, that, without limitation of Section 4.2(a), the foregoing limitations in this Section 4.2(b) shall not prohibit or limit any Disposition of Registrable Securities by a Holder as part of an Underwritten Offering with respect to such Registrable Securities in accordance with Section 2 hereof. This Section 4.2(b) shall, effective as of the date of this Agreement, supersede and replace Section 5.3(a) of the Aventis Stock Purchase Agreement. The foregoing sentence shall not impair the rights of the Company or constitute a waiver by the Company of any breach or default by Aventis or any of its Affiliates under such Section 5.3(a) with respect to events or circumstances occurring or existing prior to the date of this Agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3479

Samsung Bioepis Exhibit 1017, pg. 3479

(c) The Purchasing Parties shall not (and shall cause their respective Affiliates not to), without the prior approval of a majority of the Company's Board of Directors, Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents to any Person if such Person is, or such Disposition would (in the case of a Disposition pursuant to Rule 144 under the Securities Act, to the knowledge of any Standstill Party) result in such Person becoming, after giving effect to such Disposition, the beneficial owner of five percent (5%) or more of the total shares of Common Stock then outstanding; provided, however, that, without limitation of Section 4.2(a), the foregoing limitation in this Section 4.2(c) shall not prohibit or limit any Disposition of Registrable Securities by a Holder as part of a registered offering with respect to such Registrable Securities in accordance with Section 2 hereof.

4.3 Certain Tender Offers. Notwithstanding any other provision of this Section 4, this Section 4 shall not prohibit or restrict any Disposition of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents by the Standstill Parties into (a) a tender offer by a Third Party which is not opposed by the Company's Board of Directors (but only after the Company's filing of a Schedule 14D-9, or any amendment thereto, with the SEC disclosing the recommendation of the Company's Board of Directors with respect to such tender offer) or (b) an issuer tender offer by the Company.

4.4 Offering Lock-Up. The Holders shall, if requested by the Company and an underwriter of Common Stock of the Company, agree not to Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents for a specified period of time, such period of time not to exceed ninety (90) days. Such agreement shall be in writing in a form satisfactory to the Company and the underwriter(s) in such offering. The Company may impose stop transfer instructions with respect to the Shares of Then Outstanding Common Stock and/or Common Stock Equivalents subject to the foregoing restrictions until the end of the specified period of time. This Section 4.4 shall, effective as of the date of this Agreement, supersede and replace Section 5.3(c) of the Aventis Stock Purchase Agreement.

5. Voting Agreement.

5.1 Voting of Securities. From and after the date of this Agreement, other than as permitted by Section 5.2 with respect to Extraordinary Matters, in any vote or action by written consent of the stockholders of the Company (including, without limitation, with respect to the election of directors), the Purchaser Parties shall, and shall cause their respective Affiliates to, vote or execute a written consent with respect to all voting securities of the Company as to which they are entitled to vote or execute a written consent, in the sole discretion of the Purchaser Parties, either (a) in accordance with the recommendation of the Company's Board of Directors or (b) if such Purchaser Party or Affiliate of a Purchaser Party has delivered written notice to the Company at any time prior to the vote on any given matter or the effective time of an action to be taken by written consent, setting forth its intent to vote pursuant to this Section 5.1(b), in the same proportion as the votes cast by all other holders of all classes of voting securities of the Company (as estimated by the inspector of election immediately prior to the closing of the polls with respect to the vote on any given matter, subject to adjustment for the inspector of election's final tabulation of votes cast). In the event that a Purchaser Party or Affiliate of a Purchaser Party does not deliver written notice to the Company as provided in Section 5.1(b), such Person shall be deemed to have elected to vote all voting securities of the Company as to which it is

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3480

Samsung Bioepis Exhibit 1017, pg. 3480

entitled to vote as provided in Section 5.1(a). In furtherance of this Section 5.1, the Purchaser Parties shall, and shall cause their respective Affiliates to, if and when requested by the Company from time to time, promptly execute and deliver to the Company an irrevocable proxy, substantially in the form of Exhibit A attached hereto, and irrevocably appoint the Company or its designees, with full power of substitution, its attorney, agent and proxy to vote (or cause to be voted) or to give consent with respect to, all of the voting securities of the Company as to which such Purchaser Party or Affiliate of a Purchaser Party is entitled to vote, in the manner and with respect to the matters set forth in this Section 5.1. The Purchaser Parties acknowledge, and shall cause their Affiliates to acknowledge, that any such proxy executed and delivered shall be coupled with an interest, shall constitute, among other things, an inducement for the Company to enter into this Agreement, shall be irrevocable and binding on any successor in interest of such Purchaser Party or Affiliate of such Purchaser Party, as applicable, and shall not be terminated by operation of Law upon the occurrence of any event. Such proxy shall operate to revoke and render void any prior proxy as to any voting securities of the Company heretofore granted by such Purchaser Party or Affiliate of such Purchaser Party, as applicable, to the extent it is inconsistent herewith. Such proxy shall terminate upon the earlier of the expiration or termination of this Section 5.1.

5.2 Certain Extraordinary Matters. The Purchaser Parties and their Affiliates may vote, or execute a written consent with respect to, any or all of the voting securities of the Company as to which they are entitled to vote or execute a written consent, as they may determine in their sole discretion, with respect to the following matters (each such matter being an "Extraordinary Matter"):

(a) any transaction which would result in a Change of Control;

(b) any vote of the Company's stockholders with respect to any stock option or stock purchase plan, or any material amendment thereto, or other equity compensation arrangement or material amendment thereto, which has been approved by the Company's Compensation Committee and taken as a whole is not generally and materially consistent with the Company's equity compensation historical practices;

(c) any other issuance of shares of Common Stock or Common Stock Equivalents voted upon by stockholders of the Company that equals or exceeds ten percent (10%) of, or ten percent (10%) of the voting power of, the Shares of Then Outstanding Common Stock, as of immediately prior to such issuance; and

(d) any liquidation or dissolution of the Company.

5.3 Quorum. In furtherance of Section 5.1, the Purchaser Parties shall be, and shall cause each of their Affiliates to be, present in person or represented by proxy at all meetings of stockholders to the extent necessary so that all voting securities of the Company as to which they are entitled to vote shall be counted as present for the purpose of determining the presence of a quorum at such meeting.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3481

Samsung Bioepis Exhibit 1017, pg. 3481

6. Termination of Certain Rights and Obligations.

6.1 Termination of Registration Rights. Except for Section 2.10, which shall survive until the expiration of any applicable statutes of limitation, Section 2 shall terminate automatically and have no further force or effect upon the earliest to occur of:

(a) the expiration of the Registration Rights Term;

(b) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and

(c) a liquidation or dissolution of the Company.

6.2 Termination of Standstill Agreement. Provided that none of the Standstill Parties has violated Section 3.1(c), (d) or (f) with respect to the Offeror referred to in this Section 6.2, Section 3 (except for Section 3.2, but only to the extent such Section 3.2 amends Section 19.5 of the Aventis Collaboration Agreement) shall terminate and have no further force or effect, upon the earliest to occur of:

(a) the public announcement by an Offeror of an Acquisition Proposal for the Company;

(b) the public announcement by the Company or any Offeror of any definitive agreement providing for a Change of Control of the Company;

(c) the expiration of the Standstill Term;

(d) the date of any issuance by the Company to a Third Party of shares of Common Stock, which, when combined with all other Shares of Then Outstanding Common Stock beneficially owned by such Third Party immediately prior to such issuance, represents more than ten percent (10%) of the voting power represented by all Shares of Then Outstanding Common Stock outstanding immediately after giving effect to such issuance, if the Company does not enter into a standstill agreement with such Third Party having material terms substantially similar (i) with respect to restrictions on such Third Party, to the restrictions on the Standstill Parties set forth in Section 3.1 of this Agreement and (ii) with respect to the termination of such restrictions, to the provisions of this Section 6.2; provided, however, that any collaborative or other commercial arrangements between the Company and such Third Party entered into connection with such issuance of Common Stock to such Third Party shall be taken into consideration in determining whether the terms of the standstill agreement entered into with such Third Party are materially similar to the terms of Section 3.1 of this Agreement;

(e) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and

(f) a liquidation or dissolution of the Company;

provided, however, that if any of the transactions referred to in (a) or (b) above terminates and the Company has not made a public announcement of its intent to solicit or engage in a

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3482

Samsung Bioepis Exhibit 1017, pg. 3482

transaction (or has announced its decision to discontinue pursuing such a transaction) the consummation of which would result in a Change of Control of the Company, then the restrictions contained in Section 3 shall again be applicable, unless a Standstill Party has announced a bona-fide Acquisition Proposal for the Company prior to such termination.

6.3 Termination of Restrictions on Dispositions. Section 4 shall terminate and have no further force or effect upon the earliest to occur of:

(a) the consummation by an Offeror of a Change of Control of the Company;

(b) a liquidation or dissolution of the Company; and

(c) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.

6.4 Termination of Voting Agreement. Section 5 shall terminate and have no further force or effect upon the earliest to occur of:

(a) the consummation by an Offeror of a Change of Control of the Company;

(b) a liquidation or dissolution of the Company;

(c) the date on which the Standstill Parties beneficially own voting securities representing less than five percent (5%) of the voting power of the Shares of Then Outstanding Common Stock; and

(d) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.

6.5 Effect of Termination. No termination pursuant to any of Sections 6.1, 6.2 or 6.3 or 6.4 shall relieve any of the parties (or the Permitted Transferee, if any) for liability for breach of or default under any of their respective obligations or restrictions under any terminated provision of this Agreement, which breach or default arose out of events or circumstances occurring or existing prior to the date of such termination.

7. Miscellaneous.

7.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. The parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

7.2 Waiver. Waiver by a party of a breach hereunder by another party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3483

Samsung Bioepis Exhibit 1017, pg. 3483

shall preclude the later exercise of any such right, power or privilege by such party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

7.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit B attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Any party may change its address by giving notice to the other parties in the manner provided above.

7.4 Entire Agreement. This Agreement and the Purchase Agreement contain the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

7.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the parties hereto.

7.6 Headings; Nouns and Pronouns; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

7.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3484

Samsung Bioepis Exhibit 1017, pg. 3484

7.8 Assignment. Neither this Agreement nor any rights or duties of a party hereto may be assigned by such party, in whole or in part, without (a) the prior written consent of the Company in the case of any assignment by the Purchaser Parties, except as provided by Section 2.12 with respect to the Investor's or Aventis' assignment to a Permitted Transferee; or (b) the prior written consent of the Purchaser Parties in the case of an assignment by the Company.

7.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

7.10 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

7.11 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

7.12 No Strict Construction. This Agreement has been prepared jointly and will not be construed against any party.

7.13 Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

7.14 Specific Performance. The Purchaser Parties hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Purchaser Parties, as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

7.15 No Conflicting Agreements. Each of the Purchaser Parties hereby represents and warrants to the Company that neither it nor any of its Affiliates is, as of the date of this Agreement, a party to, and agrees that neither it nor any of its Affiliates shall, on or after the date of this Agreement, enter into any agreement that conflicts with the rights granted to the Company in this Agreement. The Company hereby represents and warrants to each Holder that it is not, as of the date of this Agreement, a party to, and agrees that it shall not, on or after the date of this Agreement, enter into, any agreement or approve any amendment to its Organizational Documents (as defined in the Purchase Agreement) with respect to its securities that conflicts

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3485

Samsung Bioepis Exhibit 1017, pg. 3485

with the rights granted to the Holders in this Agreement. The Company further represents and warrants that the rights granted to the Holders hereunder do not in any way conflict with the rights granted to any other holder of the Company's securities under any other agreements.

(Signature Page Follows)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3486

Samsung Bioepis Exhibit 1017, pg. 3486

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

SANOFI-AVENTIS

By: /s/ Jean-Michel Levy
Name: Jean-Michel Levy
Title: Senior Vice President, Business Development

By: /s/ Laurence Debroux
Name: Laurence Debroux
Title: Senior Vice President, Chief Financial Officer

SANOFI-AVENTIS US LLC

By: /s/ Karen Linehan
Name: Karen Linehan
Title: Authorized Representative

By: /s/ Robin White
Name: Robin White
Title: Authorized Representative

AVENTIS PHARMACEUTICALS INC.

By: /s/ Karen Linehan
Name: Karen Linehan
Title: Authorized Representative

By: /s/ Robin White
Name: Robin White
Title: Authorized Representative

SANOFI-AVENTIS AMÉRIQUE DU NORD

By: /s/ Karen Linehan
Name: Karen Linehan
Title: Authorized Representative

By: /s/ Jean-Luc Renard
Name: Jean-Luc Renard
Title: Authorized Representative

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard Schleifer
Name: Leonard Schleifer
Title: President & CEO

EXHIBIT A — FORM OF IRREVOCABLE PROXY

In order to secure the performance of the duties of the undersigned pursuant to Section 5.1 of the Investor Agreement, dated as of [___], 2007 (the "Agreement"), by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amérique du Nord and Regeneron Pharmaceuticals, Inc. (the "Company"), the undersigned hereby irrevocably appoints [___] and [___], and each of them, the attorneys, agents and proxies, with full power of substitution in each of them, for the undersigned, and in the name, place and stead of the undersigned, to vote (or cause to be voted) or, if applicable, to give consent, in such manners as each such attorney, agent and proxy or his substitute shall in his sole discretion deem proper to record such vote (or consent) in the manners, and with respect to such matters as set forth in Section 5.1 of the Agreement (but in any case, in accordance with any written instruction from the undersigned, properly delivered under Section 5.1 of the Agreement, to vote or give consent as contemplated by Section 5.1(b) of the Agreement) with respect to all voting securities (whether taking the form of shares of Common Stock, par value $0.001 per share, or other voting securities of the Company), which the undersigned is or may be entitled to vote at any meeting of the Company held after the date hereof, whether annual or special and whether or not an adjourned meeting or, if applicable, to give written consent with respect thereto. This proxy is coupled with an interest, shall be irrevocable and binding on any successor in interest of the undersigned and shall not be terminated by operation of law upon the occurrence of any event. This proxy shall operate to revoke and render void any prior proxy as to voting securities heretofore granted by the undersigned which is inconsistent herewith. This proxy shall terminate upon the earlier of the expiration or termination of the voting agreement set forth in Section 5.1 of the Agreement.

[_____]
By: _____
Name:
Title:

EXHIBIT B

NOTICES

(a) If to sanofi-aventis, the Investor, Aventis or Sanofi US:

sanofi-aventis
174, avenue de France
75013 Paris
France
Attention: Chief Financial Officer

with a copy to:

sanofi-aventis
174, avenue de France
75013 Paris
France
Attention: General Counsel

(b) If to the Company:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
U.S.A.
Attention: President
Copy: General Counsel

with a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street, 31st Floor
Boston, MA 02108
Attention: Kent A. Coit

Exhibit 12.1

Regeneron Pharmaceuticals, Inc.
Computation of Ratio of Earnings to Combined Fixed Charges
(Dollars in thousands)

	2003	2004	2005	2006	2007
Earnings:					
Income (loss) from continuing operations before income (loss) from equity investee	$(107,395)	$41,565	$(95,456)	$(103,150)	$(105,600)
Fixed charges	14,108	14,060	13,687	13,643	13,708
Amortization of capitalized interest	33	78	78	73	23
Interest capitalized	(276)	—	—	—	—
Adjusted earnings	$ (93,530)	$55,703	$(81,691)	$ (89,434)	$ (91,869)
Fixed charges:					
Interest expense	$ 11,932	$12,175	$ 12,046	$ 12,043	$ 12,043
Interest capitalized	276	—	—	—	—
Assumed interest component of rental charges	1,900	1,885	1,641	1,600	1,665
Total fixed charges	$ 14,108	$14,060	$ 13,687	$ 13,643	$ 13,708
Ratio of earnings to fixed charges	(A)	3.96	(A)	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2003, 2005, 2006, and 2007 the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

	2003	2005	2006	2007
Coverage deficiency	$107,638	$95,378	$103,077	$105,577

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 33-50480, 33-85330, 33-97176, 333-33891, 333-80663, 333-61132, 333-97375, and 333-119257) and on Form S-3 (Nos. 333-74464 and 333-121225) of Regeneron Pharmaceuticals, Inc., of our report dated February 27, 2008 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP

New York, New York
February 27, 2008

Exhibit 31.1

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the registrant, particularly during the period in which this annual report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting: and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2008

By: /s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 31.2

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the registrant, particularly during the period in which this annual report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting: and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2008

By: /s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and Assistant Secretary

Exhibit 32

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
February 27, 2008

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
February 27, 2008

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-K

Filing Date: 2/26/2009

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2008

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No)*
777 Old Saw Mill River Road, Tarrytown, New York	10591-6707
(Address of principal executive offices)	*(Zip code)*

(914) 347-7000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	Nasdaq Global Select Market

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑	Accelerated filer ☐	Non-accelerated filer ☐	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $1,081,564,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2008, the last trading day of the registrant's most recently completed second fiscal quarter.

The number of shares outstanding of each of the registrant's classes of common stock as of February 13, 2009:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	2,246,698
Common Stock, $.001 par value	77,730,064

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2009 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 58 to 61 of this filing.

PART I

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the commercial success of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is now available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We also have six clinical development programs, including three late-stage clinical programs. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis, REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed in collaboration with sanofi-aventis.

We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted primarily in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Our first three antibody product candidates currently in clinical trials were developed using *VelocImmune*. Over the course of the next several years, we plan to advance an average of two to three new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3499

Samsung Bioepis Exhibit 1017, pg. 3499

Commercial Product:

ARCALYST® (rilonacept) – Cryopyrin-Associated Periodic Syndromes (CAPS)

In February 2008, we received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We shipped $10.7 million of ARCALYST to our distributors in 2008. ARCALYST is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST is the only therapy approved in the United States for patients with CAPS, a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as *CIAS1*) which encodes a protein named cryopyrin. In addition to FCAS and MWS, CAPS includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST has not been studied for the treatment of NOMID.

In March 2008, ARCALYST became available for prescription in the United States and we transitioned the patients who participated in the CAPS pivotal study from clinical study drug to commercial supplies. In 2009, we expect to ship $20-24 million of ARCALYST to our U.S. distributors. In July 2008, we submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) for ARCALYST for the treatment of CAPS in the European Union.

Clinical Programs:

1. Aflibercept (VEGF Trap) – Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are enrolling patients in four Phase 3 trials that combine aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer (the VELOUR study) in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial is evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine (the VANILLA study). A third trial is evaluating aflibercept as a 1st line treatment for metastatic androgen independent prostate cancer in combination with docetaxel/prednisone (the VENICE study). The fourth trial is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel (the VITAL study). All four trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. As of February 2009, each of the four Phase 3 trials was over one-third enrolled, and initial data from the Phase 3 program is expected in 2010. In addition, a Phase 2 study of aflibercept in 1st-line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin (the AFFIRM study) began recruiting patients in January 2009.

Aflibercept is also being studied in a Phase 2 single-agent study in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA). This trial is now fully enrolled and we expect to have initial data from this trial by mid-2009. The FDA has granted Fast Track designation to aflibercept for the treatment of SMA.

In addition, multiple exploratory studies are being conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3500

Samsung Bioepis Exhibit 1017, pg. 3500

Aflibercept Collaboration with the sanofi-aventis Group

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare also initiated a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME) in late 2008. Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and ranibizumab (Lucentis®, a registered trademark of Genentech, Inc.), an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating dosing intervals of four and eight weeks for VEGF Trap-Eye compared with ranibizumab dosed according to its U.S. label every four weeks over the first year. As needed dosing (PRN) with both agents will be evaluated in the second year of the studies. We and Bayer Healthcare expect to complete enrollment of the VIEW 1 and VIEW 2 trials in 2009 and initial data are expected in late 2010.

In August 2008, we and Bayer HealthCare AG announced the preliminary results of a Phase 2 study in wet AMD which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year. In September 2008, the complete results of this study, including additional data on reductions in the size of the active choroidal neovascularization membrane (CNV), the active lesion that is the underlying cause of vision loss in patients with wet AMD, were reported at the 2008 annual meeting of the Retina Society.

In this double-masked Phase 2 trial, patients were initially treated with either fixed monthly or quarterly dosing for 12 weeks and then continued to receive treatment for another 40 weeks on a PRN dosing schedule. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 milligrams (mg) for 12 weeks followed by PRN dosing achieved mean improvements in visual acuity versus baseline of 9.0 letters ($p<0.0001$ versus baseline) and 5.4 letters ($p<0.085$ versus baseline), respectively, at the end of one year. The proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) increased from 23% at baseline to 45% at week 52 in patients initially treated with 2.0 mg monthly and from 16% at baseline to 47% at week 52 in patients initially treated with 0.5 mg monthly. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg also achieved mean decreases in retinal thickness versus baseline of 143 microns ($p<0.0001$ versus baseline) and 125 microns ($p<0.0001$ versus baseline) at week 52, respectively.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3501

Samsung Bioepis Exhibit 1017, pg. 3501

During the week 12 to week 52 PRN dosing period, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 additional injections.

While PRN dosing following a fixed quarterly dosing regimen (with dosing at baseline and week 12) also yielded improvements in visual acuity and retinal thickness versus baseline at week 52, the results generally were not as robust as those obtained with initial fixed monthly dosing.

In this Phase 2 study, treatment with VEGF Trap-Eye was also associated with a reduction in the size of the CNV lesion. Patients initially receiving either a 2.0 mg or 0.5 mg monthly fixed dose of VEGF Trap-Eye for 12 weeks followed by PRN dosing experienced statistically significant 3.41 mm^2 and 1.42 mm^2 reductions in mean CNV size at 48 weeks (the final one-year analysis endpoint from the independent reading center) versus baseline, respectively. Patients in the 2.0 mg monthly cohort also achieved a statistically significant 1.75 mm^2 reduction in total lesion size. A reduction in total lesion size was not seen in the cohort initially dosed with 0.5 mg monthly.

In this Phase 2 study, VEGF Trap-Eye was generally well tolerated and there were no reported drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye, which was deemed not to be drug-related. The most commonly reported adverse events were those typically associated with intravitreal injections.

The recently initiated Phase 2 DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study will be enrolling approximately 200 patients in the U.S., Canada, European Union, and Australia. The patients in the study will be treated for 52 weeks followed by six additional months of safety evaluation. The primary efficacy endpoint is the change in best corrected visual acuity (BCVA) from baseline to week 24.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and other diseases and disorders. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of $75.0 million from Bayer HealthCare. In 2007, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD, and can earn up to $90 million in additional development and regulatory milestones related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

3. ARCALYST® (rilonacept) – Inflammatory Diseases

We are evaluating ARCALYST in certain diseases and disorders, in addition to CAPS, where IL-1 may play an important role. In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of ARCALYST versus placebo in the prevention of gout flares induced by the initiation of urate-lowering drug therapy that is used to control gout. In this 83-patient, double-blind, placebo-controlled study, the mean number of flares per patient over the first 12 weeks of urate-lowering therapy was 0.79 with placebo and 0.15 with ARCALYST (p=0.0011), an 81% reduction. This was the primary endpoint of the study. All secondary endpoints also were met with statistical significance. In the first 12 weeks of treatment, 45.2% of patients treated with placebo experienced a gout flare and, of those, 47.4% had more than one flare. Among patients treated with ARCALYST, only 14.6% experienced a gout flare (p=0.0037 versus placebo) and none had more than one flare. Injection-site reaction was the most commonly reported adverse event with ARCALYST and no serious drug-related adverse events were reported.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3502

Samsung Bioepis Exhibit 1017, pg. 3502

Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We are in the process of initiating a Phase 3 clinical development program with ARCALYST® (rilonacept) for the treatment of gout. Two Phase 3 clinical trials will evaluate ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. We plan to initiate a Phase 3 clinical trial of ARCALYST for acute gout that will evaluate treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The Phase 3 clinical development program will also include a separate safety study.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody, and to receive 45% of net profits on sales of the antibody product, in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe. Under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to ARCALYST.

4. Monoclonal Antibodies

We and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated using our *VelocImmune*® technology. The first therapeutic antibodies to enter clinical development under the collaboration are REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis, and REGN475, an antibody to Nerve Growth Factor (NGF) that is being developed for the treatment of pain. In addition, a Phase I trial is in the process of being initiated for REGN421, an antibody to Delta-like ligand-4 (Dll4) that is being evaluated in oncology in patients with advanced malignancies. Over the course of the next several years, we and sanofi-aventis plan to advance an average of two to three new antibodies into clinical development each year.

Research and Development Technologies:

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of secreted proteins can have clinical benefit.

Regeneron scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST, as well as aflibercept, and VEGF Trap-Eye which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite*™ is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3503

Samsung Bioepis Exhibit 1017, pg. 3503

VelociSuite™

VelociSuite consists of *VelocImmune®, VelociGene®, VelociMouse®, and VelociMab™*. The *VelocImmune* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune* was generated by exploiting our *VelociGene* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our entire *VelociSuite* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knockout models, a color or fluorescent marker is substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body, during normal body functioning, as well as in disease processes. For the optimization of pre-clinical development and toxicology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

The *VelociMouse* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, Regeneron's VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab* platform for the rapid generation of expression cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

Antibody Collaboration with sanofi-aventis

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $75 million of research from the collaboration's inception through December 31, 2008 and will fund up to $100 million per year in 2009 through 2012. Sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3504

Samsung Bioepis Exhibit 1017, pg. 3504

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene*® platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

License Agreement with AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made two $20.0 million annual, non-refundable payments to us, one in February 2007 and the other in February 2008. AstraZeneca is required to make up to four additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first two additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

License Agreement with Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made two $20.0 million annual, non-refundable payments to us, one in April 2007 and the other in June 2008. Astellas is required to make up to four additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first two additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

Academic *VelocImmune*® Investigators Program

In September 2008, we entered into an agreement that will provide researchers at Columbia University Medical Center with access to our *VelocImmune* technology platform. Under the agreement, scientists at Columbia will use *VelocImmune* mice to generate antibodies against their research targets and will conduct research to discover potential human therapeutics based on the antibodies. We have an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products and will pay Columbia a low single-digit royalty on ensuing product sales.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We are using our *VelociGene* technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our *VelociGene* technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse ES cells which can be used to produce knockout mice. These materials are available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, as amended in September 2008, we are entitled to receive a minimum of $24.5 million over the five-year period beginning September 2006, including $1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which are being supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3505

Samsung Bioepis Exhibit 1017, pg. 3505

Research Programs:

Oncology and Angiogenesis

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In 1994, we discovered a second family of angiogenic growth factors, termed Angiopoietins, and we have received patents covering members of this family. Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. Angiopoietins are being evaluated in preclinical research by us and our academic collaborators. Our preclinical studies have revealed that VEGF and Angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Manipulation of both VEGF and Angiopoietins seems to be of value in blocking vessel growth. We have research programs focusing on several targets in the areas of oncology and angiogenesis.

Tumors depend on the growth of new blood vessels (a process called "angiogenesis") to support their continued growth. Therapies that block tumor angiogenesis, specifically those that block VEGF, the key initiator of tumor angiogenesis, recently have been validated in human cancer patients. However, anti-VEGF approaches do not work in all patients, and many tumors can become resistant to such therapies.

In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. We are in the process of initiating Phase 1 clinical development of a fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune*® technology.

Metabolic and Related Diseases

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in integrating peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program in this area encompasses the study of peripheral (hormonal) regulators of food intake and metabolism in health and disease. We have identified several targets in these therapeutic areas and are evaluating potential antibodies to evaluate in preclinical studies.

Muscle Diseases and Disorders

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle research program is currently focused on conducting in vivo and in vitro experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. We have several molecules in late stage research and are evaluating them for possible further development.

Other Therapeutic Areas

We also have research programs focusing on ophthalmology, inflammatory and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3506

Samsung Bioepis Exhibit 1017, pg. 3506

Manufacturing

Our manufacturing facilities are located in Rensselaer, New York and consist of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space. At December 31, 2008, we employed 246 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2008.

Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the good manufacturing practice (GMP) regulations of the health authority. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies. If our manufacturing facilities fail to comply with FDA and other regulatory requirements, we will be required to suspend manufacturing. This would likely have a material adverse effect on our financial condition, results of operations, and cash flow.

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies (see "Risk Factors – *Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.*"). Our competitors include Genentech, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Abbott Laboratories, sanofi-aventis, Merck & Co., Amgen Inc., Roche, and others. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also be significant if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even when we achieve product commercialization, one or more of our competitors may achieve product commercialization earlier than we do or obtain patent protection that dominates or adversely affects our activities. Our ability to compete will depend on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

ARCALYST® (rilonacept). There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company, Novartis, and Xoma Ltd. are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has filed applications in the U.S. and Europe seeking regulatory approval of its IL-1 antibody in CAPS. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. These drug candidates could offer competitive advantages over ARCALYST. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYST.

Aflibercept and VEGF Trap-Eye. Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to our VEGF Trap in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate.

In particular, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and a number of pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Pfizer, and Imclone Systems Incorporated (now a wholly-owned subsidiary of Eli Lilly). Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Pfizer and Onyx Pharmaceuticals (together with its partner Bayer) are selling and marketing oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3507

Samsung Bioepis Exhibit 1017, pg. 3507

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of wet AMD, DME, and other eye indications. Lucentis was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a significant competitive challenge in this indication. The National Eye Institute initiated a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. Avastin (Genentech) is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other areas.

REGN88. We are developing REGN88 for the treatment of rheumatoid arthritis as part of our global, strategic collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex Corporation), Remicade® (Centocor, Inc.), and Humira® (Abbott), and other marketed therapies makes it difficult to successfully develop and commercialize REGN88. REGN88 is a human monoclonal antibody targeting the interleukin-6 receptor. Roche is developing Actemra™ (tocilizumab) an antibody against the interleukin-6 (IL-6) receptor. Roche's antibody is approved for marketing and sale in Europe and is the subject of a filed Biologics License Application with the FDA for the treatment of rheumatoid arthritis. Roche's IL-6 receptor antibody, other clinical candidates in development, and the drugs on the market to treat rheumatoid arthritis could offer competitive advantages over REGN88. This could delay or impair our ability to successfully develop and commercialize REGN88.

REGN421. We are also developing REGN421 for the treatment of various cancers as part of our antibody collaboration with sanofi-aventis. Many companies are developing therapeutic molecules designed to block angiogenesis. A variety of different approaches have been employed, including developing a number of antagonists to VEGF and Dll4 and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to REGN421 in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate. In particular, OncoMed Pharmaceuticals, Inc. has a Dll4 antibody in Phase 1 clinical development.

REGN475. We are also developing REGN475 for the treatment of pain as part of our antibody collaboration with sanofi-aventis. The availability of effective FDA approved non-steroidal anti-inflammatory drugs (NSAIDs) including NSAIDs available over-the-counter without a prescription, and other marketed therapies, may make it difficult to successfully develop and commercialize REGN475. REGN475 is a human monoclonal antibody targeting Nerve Growth Factor (NGF). Pfizer is also developing an antibody against NGF that is in Phase 3 clinical trials for the treatment of pain due to osteoarthritis. Pfizer's NGF antibody, other clinical candidates in development, and other drugs on the market, including over-the-counter medications, to treat pain could offer competitive advantages over REGN475, which could delay or impair our ability to successfully develop and commercialize REGN475.

Other Areas. Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics that are the focus of other research or development programs we are now conducting. These competitors include Amgen and Genentech, as well as many others. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

If a competitor announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, the announcement may have an adverse effect on our operations or future prospects or on the market price of our Common Stock.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3508

Samsung Bioepis Exhibit 1017, pg. 3508

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties or other consideration for use of their technology. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see "Risk Factors – *We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.*"). Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. We are the nonexclusive licensee of a number of additional U.S. patents and patent applications. We also rely upon trade secrets, know-how, and continuing technological innovation in an effort to develop and maintain our competitive position. We or our licensors or collaborators have filed patent applications on various products and processes relating to our product candidates as well as other technologies and inventions in the United States and in certain foreign countries. We intend to file additional patent applications, when appropriate, relating to improvements in these technologies and other specific products and processes. We plan to aggressively prosecute, enforce, and defend our patents and other proprietary technology.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process patent applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of ARCALYST® (rilonacept) and our product candidates (see "Risk Factors – *If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.*"). All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase 3, large-scale clinical trials are

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3509

Samsung Bioepis Exhibit 1017, pg. 3509

conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a Biologics License Application, or BLA, for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

Various federal, state, and foreign statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, and other aspects of pharmaceutical product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

In addition to the foregoing, our present and future business will be subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations.

Business Segments

We manage our business as one segment which includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions and the development and commercialization of these discoveries. This segment also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and our grant from the NIH, (ii) ARCALYST® (rilonacept) product sales for the treatment of CAPS, and (iii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology. Prior to 2007, our operations were managed in two business segments: research and development, and contract manufacturing. In 2006, the contract manufacturing segment included all revenues and expenses related to the commercial production of a product under a contract with Merck, which expired in October 2006. For financial information about these segments, see Note 21, "Segment Information", beginning on page F-33 in our Financial Statements.

Employees

As of December 31, 2008, we had 919 full-time employees, of whom 185 held a Ph.D. and/or M.D., or PharmD degree. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

Available Information

We make available free of charge on or through our Internet website *http://www.regeneron.com* our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3510

Samsung Bioepis Exhibit 1017, pg. 3510

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through December 31, 2008, we had a cumulative loss of $875.9 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of December 31, 2008, cash, cash equivalents, restricted cash, and marketable securities totaled $527.5 million and represented 79% of our total assets. We have invested available cash balances primarily in money market funds and U.S. Treasury, U.S. government agency, corporate, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by Statement of Financial Accounting Standards No. (SFAS) 115, *Accounting for Certain Investments in Debt and Equity Securities*. Marketable securities totaled $278.0 million at December 31, 2008, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that is charged against income. For example, during the year ended December 31, 2008, we recorded charges for other-than-temporary impairments totaling $2.5 million related to two marketable securities in our investment portfolio. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3511

Samsung Bioepis Exhibit 1017, pg. 3511

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are studying aflibercept, VEGF Trap-Eye, ARCALYST, and our antibody candidates in a wide variety of indications. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are being, or are planned to be, studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3512

Samsung Bioepis Exhibit 1017, pg. 3512

cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST in only a small number of patients with CAPS. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (Amgen, Inc.), Enbrel® (Immunex Corporation), and Remicade® (Centocor, Inc.), ARCALYST affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST may interfere with the body's ability to fight infections. Treatment with Kineret (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. These side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in approved indications.

ARCALYST® (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST. Nineteen of 55 subjects (35%) who received ARCALYST for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3513

Samsung Bioepis Exhibit 1017, pg. 3513

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST® (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3514

Samsung Bioepis Exhibit 1017, pg. 3514

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. Although we obtained regulatory approval for ARCALYST for the treatment of CAPS in the United States, we may be unable to obtain regulatory approval of ARCALYST in any other country or in any other indication. Regulatory agencies outside the United States may require additional information or data with respect to any future submission for ARCALYST for the treatment of CAPS.

If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST for the treatment of CAPS or any of our product candidates in those countries.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3515

Samsung Bioepis Exhibit 1017, pg. 3515

and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated rules and listing standards covering a variety of subjects. Compliance with these rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3516

Samsung Bioepis Exhibit 1017, pg. 3516

reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2008, which report is included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2008. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies; and
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and possible legislation which could ease the entry of competing follow-on biologics into the marketplace are examples of changes and possible changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $400 million between 2009 and 2012 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3517

Samsung Bioepis Exhibit 1017, pg. 3517

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® (rilonacept) and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the manufacture, development, or ultimate commercialization of our product candidates.

We rely on third party service providers to support the distribution of ARCALYST and many other related activities in connection with the commercialization of ARCALYST for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST for the treatment of CAPS will not be successful.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3518

Samsung Bioepis Exhibit 1017, pg. 3518

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® (rilonacept) and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures or a business interruption at our manufacturing facility in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST and our product candidates at our manufacturing facility in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, or other problems at the facility.

Certain raw materials necessary for manufacturing and formulation of ARCALYST and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3519

Samsung Bioepis Exhibit 1017, pg. 3519

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept) in this indication.

Our only approved product is ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. As a result, there may be too few patients with CAPS to profitably commercialize ARCALYST in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (beracizumab), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, Inc., and Pfizer. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3520

Samsung Bioepis Exhibit 1017, pg. 3520

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, ranibizumab (Lucentis®), for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute is conducting a Phase 3 trial comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST. This is one of the reasons we discontinued the development of ARCALYST in adult rheumatoid arthritis. In addition, even if ARCALYST is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma, and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has filed applications in the U.S. and Europe seeking regulatory approval of its IL-1 antibody in CAPS. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. Novartis has stated that its IL-1 antibody demonstrated long-lasting clinical remission in patients with CAPS and that its clinical candidate could develop into a major therapeutic advance in the treatment of CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. The successful development of these competing molecules could impair our ability to successfully commercialize ARCALYST.

We have plans to develop ARCALYST for the treatment of certain gout indications. Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST in these diseases.

The successful commercialization of ARCALYST® (rilonacept) and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have announced plans to initiate a Phase 3 program studying the use of ARCALYST for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3521

Samsung Bioepis Exhibit 1017, pg. 3521

We market and sell ARCALYST® (rilonacept) in the United States for the treatment of a group of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST. Physicians may not prescribe ARCALYST, and CAPS patients may not be able to afford ARCALYST, if third party payers do not agree to reimburse the cost of ARCALYST therapy and this would adversely affect our ability to commercialize ARCALYST profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since ARCALYST and our product candidates in clinical development, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Our move to new facilities in mid-2009 could lead to disruptions in our business operations.

We plan to move most of our laboratories and headquarters to new facilities in mid-2009. There is a risk that this physical move could lead to damage to equipment or other business assets or the loss of important data, or that we could encounter problems with our new facilities, which could disrupt or delay our business operations.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3522

Samsung Bioepis Exhibit 1017, pg. 3522

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their party patents;
- public concern as to the safety or effectiveness of ARCALYST® (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2008, our five largest shareholders plus Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, beneficially owned 55.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2008. As of December 31, 2008, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 19.1% the shares of Common Stock then outstanding. Under our investor agreement with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2012 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2008, holders of Class A Stock held 22.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, plus any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in us taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of December 31, 2008:

- our current executive officers and directors beneficially owned 13.3% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2008, and 28.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2008; and

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3523

Samsung Bioepis Exhibit 1017, pg. 3523

- our five largest shareholders plus Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, beneficially owned 55.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2008. In addition, these six shareholders held 59.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2008.

Pursuant to an investor agreement, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.*"

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3524

Samsung Bioepis Exhibit 1017, pg. 3524

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. Under our main operating lease, as amended, we currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York.

In December 2006, we entered into a new operating lease agreement (as amended in October 2007 and September 2008) to lease approximately 348,000 square feet of laboratory and office space at our current Tarrytown location, which includes approximately 118,000 square feet retained from our current space and approximately 230,000 square feet in new facilities that are under construction and expected to be completed in mid-2009. The term of the lease commenced effective June 2008 and will expire in June 2024. Under the new lease, we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In November 2007, we entered into a new operating sublease for approximately 10,000 square feet of office space in Tarrytown, New York. The lease expires in September 2009 and we have the option to extend the term for two additional terms of three months each. In April 2008, we entered into a new operating sublease for approximately 16,200 square feet of office space in Tarrytown, New York. The lease expires in March 2010 and we have the option to extend the term one additional term of six months. In October 2008, we entered into a new operating sublease for approximately 14,100 square feet of office space in Bridgewater, New Jersey. The lease commences in January 2009 and expires in July 2011.

We own facilities in Rensselaer, New York, consisting of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space.

The following table summarizes the information regarding our current real property leases:

Location	Square Footage	Expiration	Current Monthly Base Rental Charges[1]	Renewal Option Available
Tarrytown, New York[2]	130,000	June, 2009	$ 171,300	None
Tarrytown, New York[2]	230,000	June, 2024	—[3]	Three 5-year terms
Tarrytown, New York[2]	118,000	June, 2024	$ 212,200	Three 5-year terms
Tarrytown, New York[4]	10,000	September, 2009	$ 22,000	Two 3-month terms
Tarrytown, New York[4]	16,200	March, 2010	$ 32,700	One 6-month term
Bridgewater, New Jersey[5]	14,100	July, 2011	$ 21,700	None

(1) Excludes additional rental charges for utilities, taxes, and operating expenses, as defined.

(2) Upon completion of the new facilities, as described above, we will retain 118,000 square feet of space in our current facility and take over 230,000 square feet in the newly constructed buildings.

(3) Rental payments will commence in August 2009.

(4) Relates to sublease in Tarrytown, New York as described above.

(5) Relates to sublease in Bridgewater, New Jersey as described above.

We believe that our existing owned and leased facilities are adequate for ongoing research, development, manufacturing, and administrative activities. In the future, we may lease, operate, or purchase additional facilities in which to conduct expanded research and development activities and manufacturing and commercial operations.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3525

Samsung Bioepis Exhibit 1017, pg. 3525

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our security holders during the last quarter of the fiscal year ended December 31, 2008.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3526

Samsung Bioepis Exhibit 1017, pg. 3526

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The NASDAQ Global Select Market:

	High	Low
2007		
First Quarter	$22.84	$17.87
Second Quarter	28.74	17.55
Third Quarter	21.78	13.55
Fourth Quarter	24.90	16.77
2008		
First Quarter	$25.25	$15.61
Second Quarter	21.68	13.75
Third Quarter	24.00	13.29
Fourth Quarter	22.82	12.62

As of February 13, 2009, there were 479 shareholders of record of our Common Stock and 42 shareholders of record of our Class A Stock.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

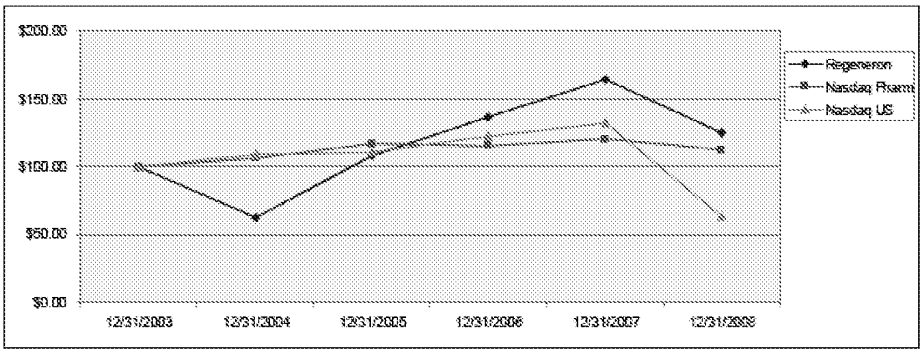
The information under the heading "Equity Compensation Plan Information" in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Report on Form 10-K.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3527

Samsung Bioepis Exhibit 1017, pg. 3527

STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) The Nasdaq Pharmaceuticals Stocks Index and (ii) The Nasdaq Stock Market (U.S.) Index for the period from December 31, 2003 through December 31, 2008. The comparison assumes that $100 was invested on December 31, 2003 in our Common Stock and in each of the foregoing indices. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices. The historical stock price performance of our Common Stock shown in the graph below is not necessarily indicative of future stock price performance.



	12/31/2003	12/31/2004	12/31/2005	12/31/2006	12/31/2007	12/31/2008
Regeneron	$100.00	$ 62.51	$108.09	$136.44	$164.17	$124.81
Nasdaq Pharm	100.00	106.51	117.29	114.81	120.74	112.34
Nasdaq US	100.00	108.84	111.16	122.11	132.42	63.80

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3528

Samsung Bioepis Exhibit 1017, pg. 3528

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2008, 2007, and 2006 and at December 31, 2008 and 2007 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2005 and 2004 and at December 31, 2006, 2005, and 2004 are derived from our audited financial statements not included in this report.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except per share data)				
Statement of Operations Data					
Revenues					
Contract research and development	$192,208	$ 96,603	$ 51,136	$ 52,447	$113,157
Research progress payments					42,770
Contract manufacturing			12,311	13,746	18,090
Technology licensing	40,000	28,421			
Net product sales	6,249				
	238,457	125,024	63,447	66,193	174,017
Expenses					
Research and development	278,016	201,613	137,064	155,581	136,095
Contract manufacturing			8,146	9,557	15,214
Selling, general, and administrative	49,348	37,865	25,892	25,476	17,062
Cost of goods sold	923				
	328,287	239,478	171,102	190,614	168,371
Income (loss) from operations	(89,830)	(114,454)	(107,655)	(124,421)	5,646
Other income (expense)					
Other contract income				30,640	42,750
Investment income	18,161	20,897	16,548	10,381	5,478
Interest expense	(7,752)	(12,043)	(12,043)	(12,046)	(12,175)
Loss on early extinguishment of debt	(938)				
	9,471	8,854	4,505	28,975	36,053
Net income (loss) before income tax expense and cumulative effect of a change in accounting principle	(80,359)	(105,600)	(103,150)	(95,446)	41,699
Income tax expense	2,351				
Net income (loss) before cumulative effect of a change in accounting principle	(82,710)	(105,600)	(103,150)	(95,446)	41,699
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")			813		
Net income (loss)	$ (82,710)	$ (105,600)	$ (102,337)	$ (95,446)	$ 41,699
Net income (loss) per share, basic:					
Net income (loss) before cumulative effect of a change in accounting principle	$ (1.05)	$ (1.59)	$ (1.78)	$ (1.71)	$ 0.75
Cumulative effect of adopting SFAS 123R			0.01		
Net income (loss)	$ (1.05)	$ (1.59)	$ (1.77)	$ (1.71)	$ 0.75
Net income (loss) per share, diluted	$ (1.05)	$ (1.59)	$ (1.77)	$ (1.71)	$ 0.74

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3529

Samsung Bioepis Exhibit 1017, pg. 3529

	At December 31,				
	2008	2007	2006	2005	2004
	(In thousands)				
Balance Sheet Data					
Cash, cash equivalents, restricted cash, and marketable securities (current and non-current)	$527,461	$846,279	$522,859	$316,654	$348,912
Total assets	670,038	936,258	585,090	423,501	473,108
Notes payable - current portion		200,000			
Notes payable - long-term portion			200,000	200,000	200,000
Stockholders' equity	418,852	460,267	216,624	114,002	182,543

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is now available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We also have six clinical development programs, including three late-stage clinical programs. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in rheumatoid arthritis, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through December 31, 2008, we had a cumulative loss of $875.9 million. In the absence of significant revenues from the commercialization of ARCALYST or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST; advance new product candidates into clinical development from our existing research programs utilizing our technologies for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

As a company that does not expect to be profitable over the next several years, management of cash flow is extremely important. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. We are reimbursed for some of these research and development activities by our collaborators. Our principal sources of cash to-date have been from (i) sales of common equity, both in public offerings and to our

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3530

Samsung Bioepis Exhibit 1017, pg. 3530

collaborators, including sanofi-aventis, (ii) a private placement of convertible debt, which was repaid in full during 2008, and (iii) funding from our collaborators in the form of up-front payments, research progress payments, and payments for our research and development activities.

In 2008, our research and development expenses totaled $278.0 million. In 2009, we expect these expenses to increase substantially as we (i) continue to expand our research and preclinical and clinical development activities in connection with our antibody collaboration with sanofi-aventis, (ii) expand our VEGF Trap-Eye, ARCALYST, and aflibercept clinical programs, and (iii) increase our research and development headcount.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2008 was 810 compared with 627 in 2007 and 573 in 2006. In 2008 our average headcount increased primarily to support our expanded research and development activities in connection with our antibody collaboration with sanofi-aventis. In 2007 our average headcount increased primarily to support our expanded development programs for VEGF Trap-Eye and ARCALYST and our plans to move our first antibody candidate into clinical trials. In 2009, we expect our average headcount to increase to approximately 950-1,000, primarily to support the further expansion of our research, development, and marketing activities as described above, especially in connection with our antibody collaboration with sanofi-aventis.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2008 and plans for 2009 are as follows:

Clinical Program	2008 Events	2009 Plans
ARCALYST® (rilonacept; also known as IL-1 Trap)	• Received FDA approval for CAPS • Launched ARCALYST commercially in CAPS • Reported data from a Phase 2 study in the prevention of gout flares in patients initiating urate-lowering drug therapy	• Initiate Phase 3 development program of ARCALYST in the prevention of gout flares in patients initiating urate-lowering drug therapy and in acute gout
Aflibercept (VEGF Trap – Oncology)	• Reported final data from Phase 2 single-agent trial in advanced ovarian cancer • Reported results from four Phase 1 dose-escalation studies in combination with chemotherapy in solid tumors • Completed enrollment of Phase 2 single-agent study in symptomatic malignant ascites (SMA)	• Initiate Phase 2 1st-line study in metastatic colorectal cancer in combination with chemotherapy • Report results of Phase 2 single-agent study in SMA • Continue enrollment of four Phase 3 studies
VEGF Trap-Eye (intravitreal injection)	• Presented positive final data through 52 weeks from the Phase 2 trial in wet AMD • Bayer HealthCare initiated second Phase 3 trial (VIEW 2) in wet AMD outside the United States • Initiated a Phase 2 study in DME	• Complete enrollment in VIEW 1 and VIEW 2 trials • Continue enrolling patients in the Phase 2 DME trial
Monoclonal Antibodies	• Filed IND for REGN421 (anti-Dll4) • Filed IND for REGN475 (anti-NGF)	• Initiate Phase 1 trial for REGN421 in oncology • Initiate Phase 1 trial for REGN475 • Report data from Phase 1 trial of REGN88 (anti-IL-6R) in rheumatoid arthritis • Advance additional antibody candidate(s) into clinical development

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3531

Samsung Bioepis Exhibit 1017, pg. 3531

Critical Accounting Policies and Use of Estimates

A summary of the significant accounting policies that impact us is provided in Note 2 to our Financial Statements, beginning on page F-7. The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- It requires an assumption (or assumptions) regarding a future outcome; and
- Changes in the estimate or the use of different assumptions to prepare the estimate could have a material effect on our results of operations or financial condition.

Management believes the current assumptions used to estimate amounts reflected in our financial statements are appropriate. However, if actual experience differs from the assumptions used in estimating amounts reflected in our financial statements, the resulting changes could have a material adverse effect on our results of operations, and in certain situations, could have a material adverse effect on our liquidity and financial condition. The critical accounting estimates that impact our financial statements are described below.

Revenue Recognition

Contract Research and Development Revenue

We recognize contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and Emerging Issues Task Force 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize our technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

We enter into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. We may share the costs of research and development activities with our collaborator, such as in our VEGF Trap-Eye collaboration with Bayer HealthCare, or we may be reimbursed for all or a significant portion of the costs of our research and development activities, such as in our aflibercept and antibody collaborations with sanofi-aventis. We record our internal and third-party development costs associated with these collaborations as research and development expenses. When we are entitled to reimbursement of all or a portion of the research and development expenses that we incur under a collaboration, we record those reimbursable amounts as contract research and development revenue proportionately as we recognize our expenses. If the collaboration is a cost-sharing arrangement in which both we and our collaborator perform development work and share costs, in periods when our collaborator incurs development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of the collaborator's development expenses that we are obligated to reimburse. In addition, we record revenue in connection with a government research grant using a proportional performance model as we incur expenses related to the grant, subject to the grant's terms and annual funding approvals.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3532

Samsung Bioepis Exhibit 1017, pg. 3532

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically and could result in material changes to the amount of revenue recognized each year in the future. In addition, our estimated performance periods may change if development programs encounter delays or we and our collaborators decide to expand or contract our clinical plans for a drug candidate in various disease indications. For example, for the year ended December 31, 2007, we recognized $2.6 million less in contract research and development revenue, compared to amounts recognized in 2006, in connection with non-refundable up-front payments previously received from sanofi-aventis pursuant to the companies' aflibercept collaboration, due to an extension of our estimated performance period. In addition, during the fourth quarter of 2008, we extended our estimated performance period in connection with the up-front and milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened our estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in our estimates resulted in the recognition of $0.4 million less in contract research and development revenue in the fourth quarter of 2008, compared to amounts recognized in connection with these deferred payments in each of the prior three quarters of 2008. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

Product Revenue

In March 2008, ARCALYST® (rilonacept) became available for prescription in the United States for the treatment of CAPS. We recognize revenue from product sales in accordance with SAB 104. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distributor fees, and other sales-related costs. We account for these reductions in accordance with Emerging Issues Task Force Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)* (EITF 01-9), and Statement of Financial Accounting Standards No. (SFAS) 48, *Revenue Recognition When Right of Return Exists,* as applicable. In accordance with EITF 01-9 and SFAS 48, since we currently have limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or we can reasonably estimate returns and (ii) rebates have been processed or we can reasonably estimate rebates. We review our estimates of rebates payable each period and record any necessary adjustments in the current period's net product sales.

Clinical Trial Expenses

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations (CROs). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts with CROs are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3533

Samsung Bioepis Exhibit 1017, pg. 3533

monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the years ended December 31, 2008 or 2007.

Stock-based Employee Compensation

We account for stock-based employee compensation under the provisions of SFAS 123R, *Share-Based Payment*. We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with previously issued employee and board of director option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

The assumptions used in computing the fair value of option awards reflect our best estimates but involve uncertainties related to market and other conditions, many of which are outside of our control. Changes in any of these assumptions may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in future periods.

In addition, we have granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, these options' performance conditions are considered to be probable of attainment.

Marketable Securities

We consider our marketable securities, which consist primarily of U.S. government, corporate, and asset-backed securities, to be "available-for-sale," as defined by SFAS 115, *Accounting for Certain Investments in Debt and Equity Securities*. These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that is charged against income.

On a quarterly basis, we review our portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. Such factors include the length of time and the extent to which market value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of our ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3534

Samsung Bioepis Exhibit 1017, pg. 3534

As a result of our quarterly reviews of our marketable securities portfolio, during 2008 and 2007, we recorded charges for other-than-temporary impairment of our marketable securities totaling $2.5 million and $5.9 million, respectively. However, the current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in our investment portfolio and that such declines could result in additional charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

Depreciation of Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. In some situations, the life of the asset may be extended or shortened if circumstances arise that would lead us to believe that the estimated life of the asset has changed. The life of leasehold improvements may change based on the extension of lease contracts with our landlords. Changes in the estimated lives of assets will result in an increase or decrease in the amount of depreciation recognized in future periods.

Results of Operations

Years Ended December 31, 2008 and 2007

Net Loss

Regeneron reported a net loss of $82.7 million, or $1.05 per share (basic and diluted), for the year ended December 31, 2008, compared to a net loss of $105.6 million, or $1.59 per share (basic and diluted) for 2007. The decrease in net loss was principally due to revenues earned in 2008 in connection with our November 2007 antibody collaboration with sanofi-aventis, partly offset by higher research and development expenses.

Revenues

Revenues for the years ended December 31, 2008 and 2007 consist of the following:

(In millions)	2008	2007
Contract research & development revenue:		
Sanofi-aventis	$154.0	$ 51.7
Bayer HealthCare	31.2	35.9
Other	7.0	9.0
Total contract research & development revenue	192.2	96.6
Technology licensing revenue	40.0	28.4
Net product sales	6.3	
Total revenue	$238.5	$125.0

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3535

Samsung Bioepis Exhibit 1017, pg. 3535

The contract research and development revenue we earn from sanofi-aventis, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Contract Research & Development Revenue	Years ended December 31, 2008	2007
(In millions)		
Aflibercept:		
Regeneron expense reimbursement	$ 35.6	$38.3
Recognition of deferred revenue related to up-front payments	8.8	8.8
Total aflibercept	44.4	47.1
Antibody:		
Regeneron expense reimbursement	97.9	3.7
Recognition of deferred revenue related to up-front payment	10.5	0.9
Recognition of revenue related to *VelociGene*® agreement	1.2	
Total antibody	109.6	4.6
Total sanofi-aventis contract research & development revenue	$154.0	$51.7

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in 2008 compared to 2007, primarily due to lower costs related to manufacturing aflibercept clinical supplies. Recognition of deferred revenue relates to sanofi-aventis' up-front aflibercept payments. As of December 31, 2008, $52.4 million of the original $105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2008, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of $72.2 million under the discovery agreement and $25.7 million of development costs, related primarily to REGN88, under the license agreement, compared to $3.0 million and $0.7 million respectively, in 2007. Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' $85.0 million up-front payment. As of December 31, 2008, $73.6 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in August 2008, we entered into a separate *VelociGene* agreement with sanofi-aventis. For the year ended December 31, 2008, we recognized $1.2 million in revenue related to this agreement.

The contract research and development revenue we earn from Bayer HealthCare, as detailed below, consists partly of cost sharing of Regeneron VEGF Trap-Eye development expenses and partly of recognition of revenue related to a non-refundable $75.0 million up-front payment and $20.0 million milestone payment.

Bayer HealthCare Contract Research & Development Revenue	Years ended December 31, 2008	2007
(In millions)		
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$18.8	$20.0
Recognition of deferred revenue related to up-front and milestone payments	12.4	15.9
Total Bayer HealthCare contract research & development revenue	$31.2	$35.9

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue. In the fourth quarter of 2007, we and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps, timelines, and costs, as well as the projected responsibilities of each of the companies. In addition, in the fourth quarter of 2007, we and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. The $75.0 million up-front licensing payment and the $20.0 million milestone payment (which was received in August 2007 and not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3536

Samsung Bioepis Exhibit 1017, pg. 3536

over the related estimated performance period. In periods when we recognize VEGF Trap-Eye development expenses that we incur under the collaboration, we also recognize, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare decreased in 2008 compared to 2007. Under the terms of the collaboration, in 2008, the first $70.0 million of agreed-upon VEGF Trap-Eye development expenses incurred by Regeneron and Bayer HealthCare under a global development plan were shared equally, and we were solely responsible for up to the next $30.0 million. Since both we and Bayer HealthCare incurred higher VEGF Trap-Eye development expenses in 2008 compared to 2007, during the fourth quarter of 2008, we were solely responsible for most of the collaboration's VEGF Trap-Eye development expenses, which partly contributed to the revenue decrease in 2008 compared to 2007. In addition, the decrease was due in part to the cumulative catchup recognized in 2007 from the inception of the collaboration in October 2006, as described above. Recognition of deferred revenue related to Bayer HealthCare's $75.0 million up-front and $20.0 million milestone payments also decreased in 2008 from 2007 as a result of the cumulative catch-up. As of December 31, 2008, $66.7 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes $4.9 million and $5.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. For the years ended December 31, 2008 and 2007, we recognized $40.0 million and $28.4 million, respectively, of technology licensing revenue related to these agreements.

For the year ended December 31, 2008, we recognized as revenue $6.3 million of ARCALYST® (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated. At December 31, 2008, deferred revenue related to ARCALYST net product sales totaled $4.0 million.

Expenses

Total operating expenses increased to $328.3 million in 2008 from $239.5 million in 2007. Our average headcount in 2008 increased to 810 from 627 in the same period of 2007 principally as a result of our expanding research and development activities which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2008 and 2007 include a total of $32.5 million and $28.1 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the year ended December 31, 2008		
Expenses	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
(In millions)			
Research and development	$259.0	$19.0	$278.0
Selling, general, and administrative	35.9	13.5	49.4
Cost of goods sold	0.9		0.9
Total operating expenses	$295.8	$32.5	$328.3

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3537

Samsung Bioepis Exhibit 1017, pg. 3537

Expenses	For the year ended December 31, 2007 Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
(In millions)			
Research and development	$185.4	$16.2	$201.6
Selling, general and administrative	26.0	11.9	37.9
Total operating expenses	$211.4	$28.1	$239.5

The increase in total Non-cash Compensation Expense in 2008 was partly attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2007 in comparison to the fair market value of annual employee option grants made in recent years prior to 2006. In addition, Non-cash Compensation Expense in 2008 and 2007 included $2.2 million and $0.1 million, respectively, in connection with a December 2007 Restricted Stock award.

Research and Development Expenses

Research and development expenses increased to $278.0 million for the year ended December 31, 2008 from $201.6 million for 2007. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2008 and 2007:

Research and Development Expenses	Year Ended December 31, 2008	2007	Increase
(In millions)			
Payroll and benefits[1]	$ 81.7	$ 60.6	$ 21.1
Clinical trial expenses	49.3	37.6	11.7
Clinical manufacturing costs[2]	53.8	47.0	6.8
Research and preclinical development costs	29.6	23.2	6.4
Occupancy and other operating costs	33.6	22.6	11.0
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses[3]	30.0	10.6	19.4
Total research and development	$278.0	$201.6	$ 76.4

(1) Includes $16.7 million and $13.2 million of Non-cash Compensation Expense for the years ended December 31, 2008 and 2007, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $2.3 million and $3.0 million of Non-cash Compensation Expense for the years ended December 31, 2008 and 2007, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, we commenced recognizing cost-sharing of our and Bayer Healthcare's VEGF Trap-Eye development expenses.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, which includes our VIEW 1 trial in wet AMD, (ii) ARCALYST® (rilonacept), which includes our Phase 2 gout flare prevention clinical study, and (iii) monoclonal antibodies, which includes REGN88 as well as clinical-related preparatory activities for REGN421. Clinical manufacturing costs increased due primarily to higher expenses related to VEGF Trap-Eye and monoclonal antibodies, including REGN88. These increases were partially offset by a reduction in manufacturing costs associated with ARCALYST and aflibercept. Research and preclinical development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new operating lease for our Tarrytown, New York facilities, which commenced in June 2008. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD, which Bayer HealthCare initiated in 2008.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3538

Samsung Bioepis Exhibit 1017, pg. 3538

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	Year ended December 31,		
Project Costs	2008	2007	Increase (Decrease)
(In millions)			
ARCALYST® (rilonacept)	$ 39.2	$ 38.1	$ 1.1
Aflibercept	32.1	33.7	(1.6)
VEGF Trap-Eye	82.7	53.7	29.0
REGN88	21.4	13.6	7.8
Other research programs & unallocated costs	102.6	62.5	40.1
Total research and development expenses	$278.0	$201.6	$ 76.4

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators, where applicable, continue to explore further development of ARCALYST, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors", under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. As a result, we can not predict whether the commercialization of ARCALYST in CAPS will result in a significant net cash benefit to us.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3539

Samsung Bioepis Exhibit 1017, pg. 3539

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $49.4 million in 2008 from $37.9 million in the same period of 2007. In 2008, we incurred $5.2 million of selling expenses related to ARCALYST® (rilonacept) for the treatment of CAPS. General and administrative expenses increased in 2008 due to (i) higher compensation expense primarily resulting from increases in administrative headcount to support our expanded research and development activities, (ii) higher recruitment and related costs associated with expanding our headcount, (iii) higher fees for professional services related to various general corporate matters, and (iv) higher administrative facility-related costs.

Cost of Goods Sold

During the year ended December 31, 2008, we began recognizing revenue and cost of goods sold from net product sales of ARCALYST. We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not being included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold for 2008 was $0.9 million and consisted primarily of royalties and other period costs related to ARCALYST commercial supplies.

Other Income and Expense

Investment income decreased to $18.2 million in 2008 from $20.9 million in the 2007, due primarily to lower yields on our cash and marketable securities. In addition, in 2008 and 2007, deterioration in the credit quality of specific marketable securities in our investment portfolio subjected us to the risk of not being able to recover these securities' carrying values. As a result, in 2008 and 2007, we recognized charges of $2.5 million and $5.9 million related to securities from three issuers and two issuers, respectively, which we considered to be other than temporarily impaired. In 2008, these charges were partially offset by realized gains of $1.2 million on sales of marketable securities during the year.

Interest expense of $7.8 million and $12.0 million for the years ended December 31, 2008 and 2007, respectively, was attributable to our 5.5% Convertible Senior Subordinated Notes due October 17, 2008. During the second and third quarters of 2008, we repurchased a total of $82.5 million in principal amount of these convertible notes for $83.3 million. In connection with these repurchases, we recognized a $0.9 million loss on early extinguishment of debt, representing the premium paid on the notes plus related unamortized debt issuance costs. The remaining $117.5 million of convertible notes were repaid in full upon their maturity in October 2008.

Income Tax Expense

In the third quarter of 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards, that would otherwise have expired over the next several years, to offset income for tax purposes. As a result, we incurred and paid income tax expense of $3.1 million, which relates to U.S. federal and New York State alternative minimum tax and included $0.2 million of interest and penalties. This expense was partly offset by a $0.7 million income tax benefit, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

Years Ended December 31, 2007 and 2006

Net Loss

Regeneron reported a net loss of $105.6 million, or $1.59 per share (basic and diluted), for the year ended December 31, 2007, compared to a net loss of $102.3 million, or $1.77 per share (basic and diluted), for 2006.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3540

Samsung Bioepis Exhibit 1017, pg. 3540

Revenues

Revenues for the years ended December 31, 2007 and 2006 consist of the following:

(In millions)	2007	2006
Contract research & development revenue:		
Sanofi-aventis	$ 51.7	$47.8
Bayer HealthCare	35.9	
Other	9.0	3.3
Total contract research & development revenue	96.6	51.1
Contract manufacturing revenue		12.3
Technology licensing revenue	28.4	
Total revenue	$125.0	$63.4

We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

	Years ended December 31,	
Sanofi-aventis Contract Research & Development Revenue	2007	2006
(In millions)		
Aflibercept:		
Regeneron expense reimbursement	$38.3	$36.4
Recognition of deferred revenue related to up-front payments	8.8	11.4
Total aflibercept	47.1	47.8
Antibody:		
Regeneron expense reimbursement	3.7	
Recognition of deferred revenue related to up-front payment	0.9	
Total antibody	4.6	
Total sanofi-aventis contract research & development revenue	$51.7	$47.8

Sanofi aventis' reimbursement of Regeneron's aflibercept expenses increased in 2007 compared to 2006, primarily due to higher preclinical and clinical development costs. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments decreased in 2007 from 2006 due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of December 31, 2007, $61.2 million of the original $105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2007, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of $3.0 million under the collaboration's discovery agreement and $0.7 million of REGN88 development costs under the license agreement. Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' $85.0 million up-front payment. As of December 31, 2007, $84.1 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in the fourth quarter of 2007, we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up. As a result, in the fourth quarter of 2007, we recognized contract research and development revenue of $35.9 million, consisting of (i) $15.9 million related to the $75.0 million up-front licensing payment and the $20.0 million milestone payment, and (ii) $20.0 million related to the portion of our 2007 VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. As of December 31, 2007, $79.1 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3541

Samsung Bioepis Exhibit 1017, pg. 3541

Other contract research and development revenue includes $5.5 million and $0.5 million in 2007 and 2006, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue in 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in 2006 was $1.2 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the $20.0 million non-refundable, up-front payment, which we received in February 2007, was deferred and recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the $20.0 million non-refundable, up-front payment, which we received in April 2007, was deferred and recognized as revenue ratably over the twelve month period beginning in June 2007. For the year ended December 31, 2007, we recognized $28.4 million of technology licensing revenue related to these agreements.

Expenses

Total operating expenses increased to $239.5 million in 2007 from $171.1 million in 2006. Our average employee headcount in 2007 increased to 627 from 573 in 2006, primarily to support our expanded development programs for VEGF Trap-Eye and ARCALYST® (rilonacept) and our activities to move our first antibody candidate (REGN88) into clinical trials. Operating expenses in 2007 and 2006 include a total of $28.1 million and $18.6 million of Non-cash Compensation Expense, as detailed below:

	For the year ended December 31, 2007		
Expenses	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
(In millions)			
Research and development	$185.4	$16.2	$201.6
Selling, general, and administrative	26.0	11.9	37.9
Total operating expenses	$211.4	$28.1	$239.5

	For the year ended December 31, 2006		
Expenses	Expenses before inclusion of Non-cash Compensation Expense	Non cash Compensation Expense	Expenses as Reported
(In millions)			
Research and development	$126.7	$10.4	$137.1
Contract manufacturing	7.8	0.3	8.1
Selling, general, and administrative	18.0	7.9	25.9
Total operating expenses	$152.5	$18.6	$171.1

The increase in total Non-cash Compensation Expense in 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3542

Samsung Bioepis Exhibit 1017, pg. 3542

Research and Development Expenses

Research and development expenses increased to $201.6 million for the year ended December 31, 2007 from $137.1 million for 2006. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2007 and 2006:

	Year Ended December 31,		
Research and Development Expenses	2007	2006	Increase
(In millions)			
Payroll and benefits[1]	$ 60.6	$ 44.8	$15.8
Clinical trial expenses	37.6	14.9	22.7
Clinical manufacturing costs[2]	47.0	39.2	7.8
Research and preclinical development costs	23.2	17.5	5.7
Occupancy and other operating costs	22.6	20.7	1.9
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses[3]	10.6		10.6
Total research and development	$201.6	$137.1	$64.5

(1) Includes $13.2 million and $8.6 million of Non-cash Compensation Expense for the years ended December 31, 2007 and 2006, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $3.0 million and $1.8 million of Non-cash Compensation Expense for the years ended December 31, 2007 and 2006, respectively.

(3) In the fourth quarter of 2007, when we commenced recognizing cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, we recognized as additional research and development expense a cumulative catch-up of $10.6 million of VEGF Trap-Eye development expenses that we were obligated to reimburse to Bayer HealthCare.

Payroll and benefits increased primarily due to the increase in employee headcount, as described above, annual compensation increases effective in 2007, and higher Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to higher costs related to our Phase 3 study of VEGF Trap-Eye in wet AMD, which we initiated in the third quarter of 2007, and our ongoing Phase 1 and 2 studies of VEGF Trap-Eye in wet AMD. Clinical manufacturing costs increased due primarily to higher costs related to manufacturing ARCALYST and preclinical and clinical supplies of REGN88, which were partly offset by lower costs related to manufacturing aflibercept and VEGF Trap-Eye. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs, including REGN88, and utilization of our proprietary technology platforms. Occupancy and other operating costs increased primarily as a result of higher Company headcount and our expanded research and development activities.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	Year ended December 31,		
Project Costs	2007	2006	Increase
(In millions)			
ARCALYST®(rilonacept)	$ 38.1	$ 29.6	$ 8.5
Aflibercept	33.7	30.7	3.0
VEGF Trap-Eye	53.7	21.9	31.8
REGN88	13.6		13.6
Other research programs & unallocated costs	62.5	54.9	7.6
Total research and development expenses	$201.6	$137.1	$64.5

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3543

Samsung Bioepis Exhibit 1017, pg. 3543

For the reasons described above in Results of Operations for the years ended December 31, 2008 and 2007, under the caption "Research and Development Expenses", and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. As a result, we can not predict whether the commercialization of ARCALYST in CAPS will result in a significant net cash benefit to us.

Contract Manufacturing Expenses

We had no contract manufacturing expenses in 2007 compared to $8.1 million in 2006, due to the expiration of our manufacturing agreement with Merck in October 2006.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $37.9 million in 2007 from $25.9 million in the same period of 2006 primarily due to (i) higher Non-cash Compensation Expense, as described above, (ii) higher compensation expense principally due to annual increases effective in 2007 and higher administrative headcount to support our expanded research and development activities, (iii) recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) market research and related expenses incurred in 2007 in connection with our ARCALYST and VEGF Trap-Eye programs.

Other Income and Expense

Investment income increased to $20.9 million in 2007 from $16.5 million in 2006, resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). This increase was partly offset by a $5.9 million charge in 2007 related to marketable securities which we considered to be other than temporarily impaired in value. In the second half of 2007, deterioration in the credit quality of marketable securities from two issuers has subjected us to the risk of being unable to recover their full principal value, which totals $14.0 million. Interest expense was $12.0 million in 2007 and 2006. Interest expense was attributable primarily to our 5.5% Convertible Senior Subordinated Notes due October 17, 2008.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, and our technology licensing agreements, ARCALYST product revenue, and investment income.

Years Ended December 31, 2008 and 2007

At December 31, 2008, we had $527.5 million in cash, cash equivalents, restricted cash and marketable securities compared with $846.3 million at December 31, 2007. Under the terms of our non-exclusive license agreements with AstraZeneca and Astellas, each company made two $20.0 million annual, non-refundable payments to us, one in 2007 and the other in 2008. In August 2007, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in our Phase 3 study of VEGF Trap-Eye in wet AMD. In December 2007, we received an $85.0 million upfront payment in connection with our new antibody collaboration with sanofi-aventis. Sanofi-aventis also purchased 12 million newly issued, unregistered shares of our Common Stock in December 2007 for gross proceeds to us of $312.0 million.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3544

Samsung Bioepis Exhibit 1017, pg. 3544

Cash (Used in) Provided by Operations

Net cash used in operations was $89.1 million in 2008, and net cash provided by operations was $27.4 million in 2007 and $23.1 million in 2006. Our net losses of $82.7 million in 2008, $105.6 million in 2007, and $102.3 million in 2006 included $32.5 million, $28.1 million, and $18.7 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of $11.3 million, $11.5 million, and $14.6 million in 2008, 2007, and 2006, respectively.

At December 31, 2008, accounts receivable increased by $16.9 million, compared to end-of-year 2007, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, prepaid expenses and other assets increased by $6.6 million at December 31, 2008 compared to end-of-year 2007 due to a $12.5 million payment to Cellectis S.A. in July 2008, described below, which is being amortized in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis. Our deferred revenue balances at December 31, 2008 decreased by $26.8 million, compared to end-of-year 2007, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by the deferral of $4.0 million of ARCALYST® (rilonacept) net product sales at December 31, 2008.

At December 31, 2007, accounts receivable increased by $10.8 million compared to end-of-year 2006 due to higher receivable balances related to our collaborations with sanofi-aventis and Bayer HealthCare. Also, prepaid expenses and other assets increased $9.6 million at December 31, 2007 compared to end-of-year 2006 due primarily to higher prepaid clinical trial costs. Our deferred revenue balances at December 31, 2007 increased by $89.8 million, compared to end-of-year 2006, due primarily to (i) the $85.0 million up-front payment received from sanofi-aventis, (ii) the $20.0 million milestone payment from Bayer HealthCare which was deemed to be non-substantive and fully deferred, and (iii) the two $20.0 million up-front payments received from each of AstraZeneca and Astellas, all as described above, partly offset by 2007 revenue recognition, principally from amortization of these deferred payments and prior year deferred payments from sanofi-aventis and Bayer HealthCare. Accounts payable, accrued expenses, and other liabilities increased $18.2 million at December 31, 2007 compared to end-of-year 2006, primarily due to a $4.9 million cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration and higher accruals in 2007 for payroll costs and clinical-related expenses.

At December 31, 2006, accounts receivable balances decreased by $29.0 million compared to end-of-year 2005, due to the January 2006 receipt of a $25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, in connection with an amendment to our aflibercept collaboration to include Japan, and lower amounts due from sanofi aventis for reimbursement of aflibercept development expenses. Also, our deferred revenue balances at December 31, 2006 increased by $60.8 million compared to end-of-year 2005, due primarily to the October 2006 $75.0 million up-front payment from Bayer, as described above, partly offset by 2006 revenue recognition from deferred sanofi-aventis up-front payments.

The majority of our cash expenditures in 2008, 2007, and 2006 were to fund research and development, primarily related to our clinical programs and, in 2008 and 2007, our preclinical human monoclonal antibody programs. In 2008, 2007, and 2006, we made interest payments totaling $9.3 million, $11.0 million, and $11.0 million, respectively, on our convertible senior subordinated notes.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $30.8 million in 2008, and net cash used in investing activities was $85.7 million and $155.1 million in 2007 and 2006, respectively. In 2008, sales or maturities of marketable securities exceeded purchases by $65.7 million, whereas in 2007 and 2006, purchases of marketable securities exceeded sales or maturities by $67.3 million and $150.7 million, respectively. Capital expenditures in 2008 include costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December 2006 Tarrytown, New York operating lease, as described below. Capital expenditures in 2007 included the purchase of land and a building in Rensselaer for $9.0 million.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3545

Samsung Bioepis Exhibit 1017, pg. 3545

Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $192.9 million in 2008, and net cash provided by financing activities was $319.4 million and $185.4 million in 2007 and 2006, respectively. In the second and third quarters of 2008, we repurchased $82.5 million in principal amount of our convertible senior subordinated notes for $83.3 million. The remaining $117.5 million of convertible notes were repaid in full upon their maturity in October 2008. In 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of our Common Stock for gross proceeds to us of $312.0 million. In 2006, we completed a public offering of 7.6 million shares of our Common Stock and received proceeds, after expenses, of $174.6 million. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $7.9 million in 2008, $7.6 million in 2007, and $10.4 million in 2006.

Fair Value of Marketable Securities

At December 31, 2008 and 2007, we held marketable securities whose aggregate fair value totaled $278.0 million and $345.7 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	2008		2007	
Investment type	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	$113.9	41%		
U.S. government agency securities	58.3	21%	$ 50.5	15%
U.S. government-guaranteed corporate bonds	29.8	11%		
U.S. government guaranteed collateralized mortgage obligations	17.4	6%	48.8	14%
Corporate bonds	37.1	13%	110.7	32%
Asset-backed securities	17.8	7%	45.2	13%
Commercial paper			72.8	21%
Other	3.7	1%	17.7	5%
Total marketable securities	$278.0	100%	$345.7	100%

In addition, at December 31, 2008 and 2007, we had $249.5 million and $500.6 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2008, as marketable securities in our portfolio matured or paid down, we purchased primarily U.S. Treasury securities, U.S. government agency obligations and U.S. government-guaranteed debt. This shift toward higher quality securities reduced the risk profile, as well as the overall yield, of our portfolio during 2008.

In particular, we reduced the proportion of asset-backed securities in the portfolio as they deteriorated in credit quality and declined in value due to higher delinquency rates on the underlying collateral supporting these securities. Of the $17.8 million of asset-backed securities that we held at December 31, 2008, $10.0 million were backed by prime and sub-prime residential mortgages and home equity loans. The remaining $7.8 million were backed by automotive loans and credit card receivables, of which one $4.9 million security matured in February 2009. The estimated fair value of our asset-backed securities generally ranged from 80% to 95% of par value at December 31, 2008. We purchased these securities in early 2007 when they were all rated triple-A by at least one of the major rating agencies. In addition, our asset-backed securities are all senior tranches that are paid-down before other subordinated tranches as the loans in the underlying collateral are repaid. Through December 31, 2008, we continued to receive monthly payments of principal and interest on our asset-backed securities holdings. If the monthly principal and interest payments continue at approximately the current rate, we anticipate that all of the asset-backed securities in our portfolio will be repaid within the next two years, and most would be repaid in 2009. However, further deterioration of the current economic environment and/or higher delinquency rates in the underlying collateral supporting an asset-backed security in our investment portfolio could result in future impairment charges related to these securities, which could be material.

In addition, we reduced the proportion of corporate bonds in our portfolio from 32% at December 31, 2007 to 13% at December 31, 2008, due to the deterioration of the credit quality of many corporate bond issuers. At the end of 2008, we held $37.1 million of corporate bonds issued by financial services companies, of which $5.1 million matured in January 2009 and another $21.6 million are scheduled to mature by the end of 2009. During 2008, we recognized other-than-temporary impairment charges of $2.5 million related to corporate securities in our portfolio. Further deterioration in the credit quality of financial services companies whose debt we hold could result in additional impairment charges, which could be material.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3546

Samsung Bioepis Exhibit 1017, pg. 3546

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. We adopted the provisions of SFAS 157 as of January 1, 2008, for financial instruments. Although the adoption of SFAS 157 did not materially impact our financial condition, results of operations, or cash flows, we are now required to provide additional disclosures as part of our financial statements. In addition, in October 2008, the FASB issued FASB Staff Position (FSP) 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active,* which clarifies the application of SFAS 157 in a market that is not active. FSP 157-3 also reaffirms the notion of fair value as an exit price as of the measurement date. FSP 157-3 was effective upon issuance for financial statements that had not yet been issued. We adopted FSP 157-3 for the quarter ended September 30, 2008.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers are Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. We have determined that the provisions of SFAS 157 are applicable to our marketable securities, which totaled $278.0 million as of December 31, 2008. At December 31, 2008, less than 1% of our marketable securities represented Level 3 assets.

Changes in Level 3 marketable securities during the year ended December 31, 2008 were as follows:

(In millions)	Level 3 Marketable Securities
Balance January 1, 2008	$ 7.9
Settlements	(8.2)
Realized gain	1.1
Impairments	(0.7)
Balance December 31, 2008	$ 0.1

During the year ended December 31, 2008, there were no transfers of marketable securities between Level 2 and Level 3 classifications.

Our methods for valuing our marketable securities are described in Note 2 to our financial statements included in this Annual Report on Form 10-K. With respect to valuations for pricing our Level 2 marketable securities, we consider quantitative and qualitative factors such as financial conditions and near term prospects of the issuer, recommendations of the investment advisors and forecasts of economic, market, or industry trends. We also review our investment advisors' policies and procedures for valuation and, for a sample of valuations, review the inputs supporting the valuations and independently test the valuations through the use of an alternative third-party vendor. For valuations that we determine for our Level 3 marketable securities, we regularly monitor these securities and adjust their valuations as deemed appropriate based on the facts and circumstances.

Collaborations with the sanofi-aventis Group

Aflibercept

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. Sanofi-aventis made a non-refundable up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for $45.0 million.

In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In connection with this amendment, sanofi-aventis made a $25.0 million non-refundable payment to us.

In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a $25.0 million non-refundable up-front payment to us, which was

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3547

Samsung Bioepis Exhibit 1017, pg. 3547

received in January 2006. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

We have agreed to manufacture clinical supplies of aflibercept at our plant in Rensselaer, New York. Sanofi-aventis has agreed to be responsible for providing commercial scale manufacturing capacity for aflibercept.

Under the collaboration agreement, as amended, agreed upon worldwide aflibercept development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to $7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs. Since inception of the collaboration agreement through December 31, 2008, we and sanofi-aventis have incurred $446.5 million in agreed upon development expenses related to aflibercept. Currently, multiple clinical studies to evaluate aflibercept as both a single agent and in combination with other therapies in various cancer indications are ongoing, and we and sanofi-aventis plan to initiate additional aflibercept clinical studies in 2009.

Sanofi-aventis funded $35.6 million, $38.3 million, and $36.4 million, respectively, of our aflibercept development costs in 2008, 2007, and 2006, of which $6.3 million, $10.5 million, and $6.8 million, respectively, were included in accounts receivable as of December 31, 2008, 2007, and 2006. In addition, the up-front payments of $80.0 million in September 2003 and $25.0 million in January 2006 from sanofi-aventis were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2008, 2007, and 2006, we recognized $8.8 million, $8.8 million, and $11.4 million of revenue, respectively, related to these up-front payments.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of aflibercept development expenses will terminate and we will retain all rights to aflibercept.

Antibodies

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $75 million of research from the collaboration's inception through December 31, 2008 and will fund up to $100 million per year in 2009 through 2012. The discovery agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate (called Shared Phase 3 Trial Costs) will be shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3548

Samsung Bioepis Exhibit 1017, pg. 3548

development expenses that were fully funded by sanofi-aventis (or half of $27.8 million as of December 31, 2008) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the license agreement, we will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The first three therapeutic antibodies to enter clinical development under the collaboration are REGN88, that is being evaluated in rheumatoid arthritis, REGN421, that is being evaluated in oncology in patients with advanced malignancies, and REGN475, that is being evaluated in pain.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured.

In 2008 and 2007, sanofi-aventis funded $72.2 million and $3.0 million, respectively, of our expenses under the collaboration's discovery agreement and $25.7 million and $0.7 million, respectively, of our development costs, primarily for REGN88, under the license agreement. Of these amounts, $25.5 million and $3.7 million were included in accounts receivable as of December 31, 2008 and 2007, respectively. In addition, the $85.0 million up-front payment received from sanofi-aventis in December 2007 was recorded to deferred revenue and is being recognized as contract research and development revenue over the period during which we expect to perform services. In 2008 and 2007, we recognized $10.5 million and $0.9 million of revenue, respectively related to this up-front payment.

In connection with the collaboration, in August 2008, we entered into a separate agreement with sanofi-aventis to use our proprietary *VelociGene*® technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. The agreement provides for minimum annual order quantities for the term of the agreement which extends through December 2012, for which we expect to receive payments totaling a minimum of $21.5 million, of which $0.6 million had been received as of December 31, 2008.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-aventis within thirty days of the date that sanofi-aventis elects to jointly develop such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party and, in the case of the discovery agreement, a termination right for sanofi-aventis under other limited defined circumstances. Prior to December 31, 2012, sanofi-aventis has the right to terminate the discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

In December 2007, we sold sanofi-aventis 12 million newly issued, unregistered shares of Common Stock at an aggregate cash price of $312.0 million, or $26.00 per share of Common Stock. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with us, which contains certain demand rights, "standstill provisions", and other restrictions, which are more fully described in Note 8 to our Financial Statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3549

Samsung Bioepis Exhibit 1017, pg. 3549

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, VEGF Trap-Eye. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of $75.0 million. In August 2007, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD, and are eligible to receive up to $90 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. We are also eligible to receive up to an additional $135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of $63.0 million at December 31, 2008) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. Within the United States, we are responsible for any future commercialization of VEGF Trap-Eye and retain exclusive rights to any future profits from commercialization. In 2007, we initiated the VIEW 1 trial in wet AMD and, in 2008, Bayer HealthCare initiated the VIEW 2 trial in wet AMD. In addition, in late 2008, we initiated a Phase 2 study of VEGF Trap-Eye in patients with DME. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

The $75.0 million up-front payment and $20.0 million non-substantive milestone payment from Bayer HealthCare were recorded to deferred revenue. In 2008 and 2007, we recognized $12.4 million and $15.9 million, respectively, of revenue related to these deferred payments. We did not recognize revenue in connection with our collaboration with Bayer HealthCare in 2006.

Under the terms of the agreement, in 2009 and thereafter, all agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared equally. In 2008, the first $70.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next $30.0 million, which resulted in a net payment of $11.3 million to Bayer HealthCare by us in 2008. In 2007, the first $50.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next $40.0 million, which resulted in a net reimbursement of $9.4 million from Bayer HealthCare to us in 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007. At December 31, 2008 and 2007, accrued expenses included $9.8 million and $4.9 million, respectively, due to Bayer HealthCare. In addition, at December 31, 2007, accounts receivable included $2.8 million due from Bayer HealthCare.

Bayer HealthCare has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to VEGF Trap-Eye.

License Agreements with AstraZeneca and Astellas

Under these non-exclusive license agreements, AstraZeneca and Astellas each made two $20.0 million annual, non-refundable payments to us, one in 2007 and the other in 2008. AstraZeneca and Astellas are each required to make up to four additional annual payments of $20.0 million, subject to each licensee's ability to terminate its license agreement with us after making two more payments or earlier if the technology does not meet minimum performance criteria.

National Institutes of Health Grant

Under our five-year grant from the NIH, we are entitled to receive a minimum of $24.5 million over a five-year period, subject to compliance with the grant's terms and annual funding approvals, including $1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2008 and 2007, we recognized $4.9 million and $5.5 million, respectively, of revenue related to the NIH Grant, of which $1.3 million and $1.0 million, respectively, was receivable at the end of 2008 and 2007. In 2009, we expect to receive funding of approximately $5 million for reimbursement of Regeneron expenses related to the NIH Grant.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3550

Samsung Bioepis Exhibit 1017, pg. 3550

Convertible Debt

In 2001, we issued $200.0 million aggregate principal amount of convertible senior subordinated notes, which bore interest at 5.5% per annum, payable semi-annually, and that matured in October 2008. During the second and third quarters of 2008, we repurchased $82.5 million in principal amount of our notes for $83.3 million. The remaining $117.5 million of outstanding convertible notes were repaid in full upon their maturity in October 2008.

License Agreement with Cellectis

In July 2008, we and Cellectis S.A. entered into an Amended and Restated Non-Exclusive License Agreement. The amended license agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to the amended license agreement, in July 2008, we made a non-refundable $12.5 million payment to Cellectis and agreed to pay Cellectis a low single-digit royalty based on revenue received by us from any future licenses or sales of our *VelociGene*® or *VelocImmune*® products and services. No royalties are payable with respect to our *VelocImmune* license agreements with AstraZeneca and Astellas or our November 2007 collaboration with sanofi-aventis. Moreover, no royalties are payable on any revenue from commercial sales of antibodies from our *VelocImmune* technology.

We are amortizing our $12.5 million payment to Cellectis in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis. In 2008, we recognized $2.7 million of expense related to this agreement.

In July 2008, we and Cellectis also entered into a Subscription Agreement pursuant to which we purchased 368,301 ordinary shares of Cellectis in November 2008 at a price of EUR 8.63 per share (which was equivalent to $10.98 at the EUR exchange rate on the date of purchase).

Operating Lease – Tarrytown, New York Facilities

Under our main operating lease, as amended, we currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York. In December 2006, we entered into a new operating lease agreement (as amended in October 2007) to lease approximately 257,000 square feet of laboratory and office space at our current Tarrytown location, which included approximately 27,000 square feet that we currently occupy (our retained facilities) and approximately 230,000 square feet in new facilities that are currently under construction and expected to be completed in mid-2009. In September 2008, we amended the operating lease agreement to increase the amount of retained space we will lease from approximately 27,000 square feet to approximately 118,000 square feet, for an amended total under the new lease of approximately 348,000 square feet. The term of the new lease commenced effective June 2008 and will expire in June 2024. Under the new lease we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, we issued a letter of credit in the amount of $1.6 million to our landlord, which is collateralized by a $1.6 million bank certificate of deposit.

Capital Expenditures

Our additions to property, plant, and equipment totaled $34.9 million in 2008, $19.6 million in 2007, and $3.3 million in 2006. In 2009, we expect to incur approximately $50 to $60 million in capital expenditures (net of Tarrytown tenant improvement costs that will be reimbursed by our landlord in connection with our new operating lease), primarily in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and our new Tarrytown operating lease, as described above. We currently expect to incur approximately $30 million in capital expenditures in 2010.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3551

Samsung Bioepis Exhibit 1017, pg. 3551

Funding Requirements

Our total expenses for research and development from inception through December 31, 2008 have been approximately $1,630 million. We have entered into various agreements related to our activities to develop and commercialize product candidates and utilize our technology platforms, including collaboration agreements, such as those with sanofi-aventis and Bayer HealthCare, and agreements to use our *Velocigene*® technology platform. We incurred expenses associated with these agreements, which include an allocable portion of general and administrative costs, of $230.6 million, $108.2 million, and $43.4 million in 2008, 2007, and 2006, respectively.

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 50-60% of our expenditures for 2009 will be directed toward the preclinical and clinical development of product candidates, including ARCALYST® (rilonacept), aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88, REGN421, and REGN475); approximately 25-30% of our expenditures for 2009 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2009 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

We currently anticipate that in 2009 the commercialization of ARCALYST for the treatment of CAPS will not materially enhance or otherwise materially impact our cash flows.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2008. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

	Payments Due by Period				
	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
	(In millions)				
Operating leases[1]	$230.1	$ 9.1	$26.8	$27.2	$167.0
Purchase obligations[2]	126.3	65.7	59.3	1.3	
Total contractual obligations	$356.4	$74.8	$86.1	$28.5	$167.0

(1) Includes projected obligations based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities under construction in Tarrytown, New York, as described above. Excludes future contingent rental costs for utilities, real estate taxes, and operating expenses. In 2008, these costs were $8.4 million.

(2) Purchase obligations primarily relate to (i) research and development commitments, including those related to clinical trials, (ii) capital expenditures for equipment acquisitions, and (iii) license payments. Our obligation to pay certain of these amounts may increase or be reduced based on certain future events. Open purchase orders for the acquisition of goods and services in the ordinary course of business are excluded from the table above.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare will share agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as described above. In addition, under our collaboration agreements with sanofi-aventis and Bayer HealthCare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by sanofi-aventis and Bayer HealthCare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for our aflibercept collaboration with sanofi-aventis, royalties on product sales in Japan) otherwise payable to us unless we agree to reimburse these expenses at a faster rate at our option. Given the uncertainties related to drug development (including the development of aflibercept and co-developed antibody candidates in collaboration with sanofi-aventis and VEGF Trap-Eye in collaboration with Bayer HealthCare) such

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3552

Samsung Bioepis Exhibit 1017, pg. 3552

as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer HealthCare will become profitable.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST® (rilonacept) for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates.

Other than letters of credit totaling $1.7 million, including a $1.6 million letter of credit issued to our landlord in connection with our operating lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of December 31, 2008, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In November 2007, the Emerging Issues Task Force issued Statement No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and will be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. We are required to adopt EITF 07-1 for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of EITF 07-1 will have a material impact on our financial statements.

In March 2008, the FASB issued SFAS 161, *Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement 133*. SFAS 161 enhances required disclosures regarding derivatives and hedging activities, including enhanced disclosures regarding how (a) an entity uses derivative instruments, (b) derivative

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3553

Samsung Bioepis Exhibit 1017, pg. 3553

instruments and related hedged items are accounted for under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, and (c) derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years and interim periods beginning after November 15, 2008. We are required to adopt SFAS 161 for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of SFAS 161 will have a material impact on our financial statements.

In April 2008, the FASB issued FASB Staff Position (FSP) FAS 142-3, *Determination of the Useful Life of Intangible Assets*. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R, and other generally accepted accounting principles (GAAP). This FSP is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. We are required to adopt FSP FAS 142-3 for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of this FSP will have a material impact on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in U.S. government, corporate, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent unfavorable change in interest rates would result in approximately a $1.9 million decrease in the fair value of our investment portfolio at both December 31, 2008 and 2007.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. In the second half of 2007, we recognized a $5.9 million charge related to marketable securities from two issuers which we considered to be other than temporarily impaired in value. In 2008, an additional $0.7 million impairment charge was recognized related to one of these securities and a $1.8 million charge was recognized related to another marketable security which we considered to be other than temporarily impaired in value.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included on pages F-1 through F-34 of this report. The supplementary financial information required by this Item is included at pages F-34 of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3554

Samsung Bioepis Exhibit 1017, pg. 3554

it files or submits under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation our management has concluded that our internal control over financial reporting was effective as of December 31, 2008. The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

ITEM 9B. OTHER INFORMATION

None.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3555

Samsung Bioepis Exhibit 1017, pg. 3555

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our officers, directors and employees. The full text of our code of business conduct and ethics can be found on the Company's website (*http://www.regeneron.com*) under the "Corporate Governance" heading on the "About Us" page.

ITEM 11. EXECUTIVE COMPENSATION

The information called for by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and therefore have been omitted.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3556

Samsung Bioepis Exhibit 1017, pg. 3556

3. Exhibits

Exhibit Number		Description
3.1	(p)	- Restated Certificate of Incorporation, filed February 11, 2008 with the New York Secretary of State.
3.2	(a)	- By-Laws of the Company, currently in effect (amended through November 9, 2007).
10.1 +	(b)	- 1990 Amended and Restated Long-Term Incentive Plan.
10.2 +	(q)	- Amended and Restated 2000 Long-Term Incentive Plan.
10.2.1 +	(c)	- Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10.2.2 +	(c)	- Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.2.3 +	(d)	- Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.3 +		- Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Company and Leonard S. Schleifer, M.D., Ph.D.
10.4* +	(e)	- Employment Agreement, dated as of December 31, 1998, between the Company and P. Roy Vagelos, M.D.
10.5 +		- Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008.
10.6*	(f)	- IL-1 License Agreement, dated June 26, 2002, by and among the Company, Immunex Corporation, and Amgen Inc.
10.7*	(g)	- Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
10.8*	(h)	- Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.8.1*	(e)	- Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 31, 2004.
10.8.2	(i)	- Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of January 7, 2005.
10.8.3*	(j)	- Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 21, 2005.
10.8.4*	(j)	- Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S. LLC (successor in interest to Aventis Pharmaceuticals, Inc.) and Regeneron Pharmaceuticals, Inc., effective as of January 31, 2006.
10.9	(h)	- Stock Purchase Agreement, dates as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.10*	(k)	- License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
10.11*	(l)	- Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007 by and between AstraZeneca UK Limited and Regeneron Pharmaceuticals, Inc.
10.12	(m)	- Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc.
10.12.1*	(o)	- First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
10.12.2	(s)	- Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of September 30, 2008.
10.13*	(n)	- Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
10.14*	(p)	- Discovery and Preclinical Development Agreement, dated as of November 28, 2007, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.15*	(p)	- License and Collaboration Agreement, dated as of November 28, 2007, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique Du Nord and Regeneron Pharmaceuticals, Inc.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3557

Samsung Bioepis Exhibit 1017, pg. 3557

Exhibit Number		Description
10.16	(p)	- Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique Du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.
10.17	(p)	- Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and Regeneron Pharmaceuticals, Inc.
10.18*	(r)	- Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Cellectis, S.A. and Regeneron Pharmaceuticals, Inc.
10.19	(r)	- Subscription Agreement, dated as of July 1, 2008 by and between Cellectis, S.A. and Regeneron Pharmaceuticals, Inc.
12.1		- Statement re: computation of ratio of earnings to combined fixed charges of Regeneron Pharmaceuticals, Inc.
23.1		- Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1		- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2		- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32		- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

(a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.

(b) Incorporated by reference from the Company's registration statement on Form S-1 (file number 33-39043).

(c) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.

(d) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.

(e) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2004, filed March 11, 2005.

(f) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.

(g) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.

(h) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 12, 2003.

(i) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.

(j) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2005, filed February 28, 2006.

(k) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.

(l) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2006, filed March 12, 2007.

(m) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.

(n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended March 31, 2007, filed May 4, 2007.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3558

Samsung Bioepis Exhibit 1017, pg. 3558

(o) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended September 30, 2007, filed November 7, 2007.

(p) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2007, filed February 27, 2008.

(q) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc. filed June 17, 2008.

(r) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2008, filed August 1, 2008.

(s) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2008, filed November 5, 2008.

---

* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

+ Indicates a management contract or compensatory plan or arrangement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3559

Samsung Bioepis Exhibit 1017, pg. 3559

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

By: /S/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Dated: New York, New York
February 26, 2009

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Murray A. Goldberg, Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, and each of them, his true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title
/S/ LEONARD S. SCHLEIFER Leonard S. Schleifer, M.D., Ph.D.	*President, Chief Executive Officer, and Director (Principal Executive Officer)*
/S/ MURRAY A. GOLDBERG Murray A. Goldberg	*Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer)*
/S/ DOUGLAS S. MCCORKLE Douglas S. McCorkle	*Vice President, Controller, and Assistant Treasurer (Principal Accounting Officer)*
/S/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D.	*Executive Vice President, Chief Scientific Officer, President, Regeneron Research Laboratories, and Director*
/S/ P. ROY VAGELOS P. Roy Vagelos, M.D.	*Chairman of the Board*
/S/ CHARLES A. BAKER Charles A. Baker	*Director*
/S/ MICHAEL S. BROWN Michael S. Brown, M.D.	*Director*
/S/ ALFRED G. GILMAN Alfred G. Gilman, M.D., Ph.D.	*Director*
/S/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	*Director*
/S/ ERIC M. SHOOTER Eric M. Shooter, Ph.D.	*Director*
/S/ GEORGE L. SING George L. Sing	*Director*

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3560

Samsung Bioepis Exhibit 1017, pg. 3560

REGENERON PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.	Page Numbers
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets at December 31, 2008 and 2007	F-3
Statements of Operations for the years ended December 31, 2008, 2007, and 2006	F-4
Statements of Stockholders' Equity for the years ended December 31, 2008, 2007, and 2006	F-5
Statements of Cash Flows for the years ended December 31, 2008, 2007, and 2006	F-6
Notes to Financial Statements	F-7 to F-34

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3561

Samsung Bioepis Exhibit 1017, pg. 3561

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Regeneron Pharmaceuticals, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. at December 31, 2008 and December 31, 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in note 2 to the financial statements, effective January 1, 2006, the Company changed its method of accounting for share-based payment, to conform with FASB Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-based Payment."

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP

New York, New York
February 26, 2009

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3562

Samsung Bioepis Exhibit 1017, pg. 3562

REGENERON PHARMACEUTICALS, INC.
BALANCE SHEETS

December 31, 2008 and 2007

	2008	2007
	(In thousands, except share data)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 247,796	$ 498,925
Marketable securities	226,954	267,532
Accounts receivable from the sanofi-aventis Group	33,302	14,244
Accounts receivable - other	1,910	1,076
Prepaid expenses and other current assets	11,480	13,052
Total current assets	521,442	797,829
Restricted cash	1,650	1,600
Marketable securities	51,061	78,222
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	87,853	58,304
Other assets	8,032	303
Total assets	$ 670,038	$ 936,258
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 36,168	$ 39,232
Deferred revenue from sanofi-aventis, current portion	21,390	18,855
Deferred revenue - other, current portion	26,114	25,577
Notes payable		200,000
Total current liabilities	83,672	283,664
Deferred revenue from sanofi-aventis	105,586	126,431
Deferred revenue - other	56,835	65,896
Other long term liabilities	5,093	
Total liabilities	251,186	475,991
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, $.001 par value: 40,000,000 shares authorized; shares issued and outstanding - 2,248,698 in 2008 and 2,260,266 in 2007	2	2
Common Stock, $.001 par value: 160,000,000 shares authorized; shares issued and outstanding - 77,642,203 in 2008 and 76,592,218 in 2007	78	77
Additional paid-in capital	1,294,813	1,253,235
Accumulated deficit	(875,927)	(793,217)
Accumulated other comprehensive income (loss)	(114)	170
Total stockholders' equity	418,852	460,267
Total liabilities and stockholders' equity	$ 670,038	$ 936,258

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3563

Samsung Bioepis Exhibit 1017, pg. 3563

REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2008, 2007, and 2006

	2008	2007	2006
	(In thousands, except per share data)		
Revenues			
Contract research and development from sanofi-aventis	$153,972	$ 51,687	$ 47,763
Other contract research and development	38,236	44,916	3,373
Contract manufacturing			12,311
Technology licensing	40,000	28,421	
Net product sales	6,249		
	238,457	125,024	63,447
Expenses			
Research and development	278,016	201,613	137,064
Selling, general, and administrative	49,348	37,865	25,892
Contract manufacturing			8,146
Cost of goods sold	923		
	328,287	239,478	171,102
Loss from operations	(89,830)	(114,454)	(107,655)
Other income (expense)			
Investment income	18,161	20,897	16,548
Interest expense	(7,752)	(12,043)	(12,043)
Loss on early extinguishment of debt	(938)		
	9,471	8,854	4,505
Net loss before income tax expense and cumulative effect of a change in accounting principle	(80,359)	(105,600)	(103,150)
Income tax expense	2,351		
Net loss before cumulative effect of a change in accounting principle	(82,710)	(105,600)	(103,150)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")			813
Net loss	$ (82,710)	$ (105,600)	$ (102,337)
Net loss per share, basic and diluted:			
Net loss before cumulative effect of a change in accounting principle	$ (1.05)	$ (1.59)	$ (1.78)
Cumulative effect of adopting SFAS 123R			0.01
Net loss	$ (1.05)	$ (1.59)	$ (1.77)
Weighted average shares outstanding, basic and diluted	78,827	66,334	57,970

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3564

Samsung Bioepis Exhibit 1017, pg. 3564

REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2008, 2007, and 2006

	Class A Stock		Common Stock		Additional Paid-in	Unearned		Accumulated Other	Total	
	Shares	Amount	Shares	Amount	Capital	Compensation	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Equity	Comprehensive Loss
					(In thousands)					
Balance, December 31, 2005	2,347	$2	94,092	$94	$ 700,011	$(313)	$(585,280)	$(470)	$ 114,002	
Issuance of Common Stock in a public offering at $23.03 per share			7,600	8	175,020				175,028	
Cost associated with issuance of equity securities					(412)				(412)	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			1,243	1	10,391				10,392	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			121		1,884				1,884	
Conversion of Class A Stock to Common Stock	(77)		77							
Forfeiture of restricted Common Stock under Long-Term Incentive Plan			(2)							
Stock based										

compensation expense					18,641				18,641	
Adjustment to reduce unearned compensation upon adoption of SFAS 123R					(315)	315				
Cumulative effect of adopting SFAS 123R					(813)				(813)	
Net loss, 2006							(102,337)		(102,337)	$(102,337)
Change in net unrealized gain (loss) on marketable securities								239	239	239
Balance, December 31, 2006	2,270	2	83,131	83	904,407		(837,617)	(234)	216,624	$(102,098)
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			886	1	7,618				7,619	
Issuance of Common Stock to sanofi-aventis			12,000	12	311,988				312,000	
Cost associated with issuance of equity securities to sanofi-aventis					(219)				(219)	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			65		1,367				1,367	
Issuance of										

Restricted Common Stock under Long-Term Incentive Plan			500	1	(1)					
Conversion of Class A Stock to Common Stock	(10)		10							
Stock-based compensation expense					28,075				28,075	
Net loss, 2007							(105,600)		(105,600)	$(105,600)
Change in net unrealized gain (loss) on marketable securities								401	401	401
Balance, December 31, 2007	2,260	2	76,592	77	1,253,235	—	(793,210)	170	460,267	$(105,199)
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			939	1	7,948				7,949	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			59		1,107				1,107	
Conversion of Class A Stock to Common Stock	(11)		11							
Stock-based compensation expense					32,523				32,523	
Net loss, 2008							(82,710)		(82,710)	$ (82,710)
Change in net										

unrealized gain (loss) on marketable securities	—	—	—	—	—	—	—	(284)	(284)	(284)
Balance, December 31, 2008	2,249	$2	77,642	$78	$1,294,813	—	$(875,920)	$(114)	$ 418,852	$ (82,994)

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3568

Samsung Bioepis Exhibit 1017, pg. 3568

REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2008, 2007, and 2006

	2008	2007	2006
		(In thousands)	
Cash flows from operating activities			
Net loss	$ (82,710)	$(105,600)	$(102,337)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities			
Depreciation and amortization	11,287	11,487	14,592
Non-cash compensation expense	32,523	28,075	18,675
Loss on early extinguishment of debt	938		
Net realized loss on marketable securities	1,316	5,943	
Cumulative effect of a change in accounting principle			(813)
Changes in assets and liabilities			
(Increase) decrease in accounts receivable	(16,892)	(10,827)	29,028
(Increase) decrease in prepaid expenses and other assets	(6,560)	(9,649)	155
Decrease in inventory			3,594
(Decrease) increase in deferred revenue	(26,834)	89,764	60,833
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(2,148)	18,179	(652)
Total adjustments	(6,376)	132,972	125,412
Net cash (used in) provided by operating activities	(89,086)	27,372	23,075
Cash flows from investing activities			
Purchases of marketable securities	(581,139)	(594,446)	(456,893)
Sales or maturities of marketable securities	646,861	527,169	306,199
Capital expenditures	(34,857)	(18,446)	(2,811)
Increase in restricted cash	(50)		(1,600)
Net cash provided by (used in) investing activities	30,815	(85,723)	(155,105)
Cash flows from financing activities			
Repurchases or repayment of notes payable	(200,807)		
Net proceeds from the issuance of Common Stock	7,949	319,400	185,008
Other			390
Net cash (used in) provided by financing activities	(192,858)	319,400	185,398
Net (decrease) increase in cash and cash equivalents	(251,129)	261,049	53,368
Cash and cash equivalents at beginning of period	498,925	237,876	184,508
Cash and cash equivalents at end of period	$ 247,796	$ 498,925	$ 237,876
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 9,348	$ 11,000	$ 11,000
Cash paid for income taxes	$ 3,079		

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3569

Samsung Bioepis Exhibit 1017, pg. 3569

1. Organization and Business

Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") was incorporated in January 1988 in the State of New York. The Company is engaged in the research, development, and commercialization of therapeutics to treat human disorders and conditions. In 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for the Company's first commercial drug product, ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company's facilities are primarily located in New York. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, obtaining regulatory approvals, commercializing products, and obtaining and enforcing patents.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

For purposes of the statement of cash flows and the balance sheet, the Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

Marketable Securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company generally invests its excess cash in obligations of the U.S. government and its agencies, investment grade debt securities issued by corporations, governments, and financial institutions, bank deposits, asset-backed securities, commercial paper, and money market funds that invest in these instruments. The Company considers its marketable securities to be "available-for-sale," as defined by Statement of Financial Accounting Standards No. ("SFAS") 115, *Accounting for Certain Investments in Debt and Equity Securities*. These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in the Company's investment portfolio is deemed to be other-than-temporary, the Company writes down the security to its current fair value and recognizes a loss that is charged against income. As described under "Use of Estimates" below, on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary.

Capitalization of Inventory Costs

The Company does not capitalize inventory costs associated with commercial supplies of drug product until it has received marketing approval from the FDA. Prior to receipt of FDA approval, costs for manufacturing supplies of drug product are recognized as research and development expenses in the period that the costs were incurred. Therefore, these pre-approval manufacturing costs are not included in cost of goods sold when revenue is recognized from the sale of those supplies of drug product.

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. In 2008, subsequent to receipt of such marketing approval, ARCALYST shipments to the Company's customers consisted of supplies of inventory manufactured and expensed prior to FDA approval. At December 31, 2008, the Company had no inventoried costs related to ARCALYST.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3570

Samsung Bioepis Exhibit 1017, pg. 3570

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	7-30 years
Laboratory and other equipment	3-5 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the lease term, without assuming renewal features, if any, are exercised. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

Accounting for the Impairment of Long-Lived Assets

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount in accordance with SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. For all periods presented, no impairment losses were recorded.

Patents

As a result of the Company's research and development efforts, the Company has obtained, applied for, or is applying for, a number of patents to protect proprietary technology and inventions. All costs associated with patents are expensed as incurred.

Leases

The Company accounts for its lease agreements pursuant to SFAS 13, *Accounting for Leases*. On certain of its lease agreements, the Company may receive rent holidays and other incentives. The Company recognizes lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays that defer the commencement date of required payments. In addition, lease incentives that the Company receives are treated as a reduction of rent expense over the term of the related agreements.

Revenue Recognition

a. Contract Research and Development Revenue

The Company recognizes contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. ("SAB") 104, *Revenue Recognition* and Emerging Issues Task Force No. ("EITF") 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. The Company earns contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3571

Samsung Bioepis Exhibit 1017, pg. 3571

associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, such as in the Company's VEGF Trap-Eye collaboration with Bayer HealthCare LLC, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities, such as in the Company's aflibercept and antibody collaborations with the sanofi-aventis Group. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as contract research and development revenue proportionately as the Company recognizes its expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, in periods when the Company's collaborator incurs development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of the collaborator's development expenses that the Company is obligated to reimburse. In addition, the Company records revenue in connection with a government research grant using a proportional performance model as it incurs expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, estimated performance periods may change if development programs encounter delays or the Company and its collaborators decide to expand or contract the clinical plans for a drug candidate in various disease indications. For example, for the year ended December 31, 2007, the Company recognized $2.6 million less in contract research and development revenue, compared to amounts recognized in 2006, in connection with non-refundable up-front payments previously received from sanofi-aventis pursuant to the companies' aflibercept collaboration, due to an extension of the Company's estimated performance period. In addition, during the fourth quarter of 2008, the Company extended its estimated performance period in connection with the up-front and milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened its estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in the Company's estimates resulted in the recognition of $0.4 million less in contract research and development revenue in the fourth quarter of 2008, compared to amounts recognized in connection with these deferred payments in each of the prior three quarters of 2008. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, the Company would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

b. Contract Manufacturing

The Company manufactured product and performed services for a third party under a contract manufacturing agreement which expired in October 2006. Contract manufacturing revenue was recognized as product was shipped and as services were performed.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3572

Samsung Bioepis Exhibit 1017, pg. 3572

c. *VelocImmune*® Technology Licensing

The Company enters into non-exclusive license agreements with third parties that allow the third party to utilize the Company's *VelocImmune* technology in its internal research programs. The terms of these agreements include annual, non-refundable payments and entitle the Company to receive royalties on any future sales of products discovered by the third party using the Company's *VelocImmune* technology. Annual, non-refundable payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective annual license periods.

d. Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST® (rilonacept) for the treatment of CAPS. The Company recognizes revenue from product sales in accordance with SAB 104. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and the Company has no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distribution fees, and other sales-related costs. The Company accounts for these reductions in accordance with EITF 01-9, *Accounting for Considerations Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products),* and SFAS 48, *Revenue Recognition When Right of Return Exists,* as applicable. In accordance with EITF 01-9 and SFAS 48, since the Company currently has limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or the Company can reasonably estimate returns and (ii) rebates have been processed or the Company can reasonably estimate rebates. The Company reviews its estimates of rebates payable each period and records any necessary adjustments in the current period's net product sales.

Investment Income

Interest income, which is included in investment income, is recognized as earned.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements, the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by contract research organizations ("CROs"). CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these startup costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3573

Samsung Bioepis Exhibit 1017, pg. 3573

significantly wider, as many of the Company's contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates. The Company's estimates and assumptions for clinical expense recognition could differ significantly from its actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

Stock-based Employee Compensation

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment,* which is a revision of SFAS 123, *Accounting for Stock-Based Compensation*. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate, at the time of grant, the number of awards that are expected to be forfeited and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005 and prior to the Company's adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that were not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by $0.8 million and is included in the Company's operating results in 2006 as a cumulative-effect adjustment of a change in accounting principle.

Income Taxes

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain.

Comprehensive Income (Loss)

The Company presents comprehensive income (loss) in accordance with SFAS 130, *Reporting Comprehensive Income*. Comprehensive income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive income (loss) is immaterial. Comprehensive losses for the years ended December 31, 2008, 2007, and 2006 have been included in the Statements of Stockholders' Equity.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3574

Samsung Bioepis Exhibit 1017, pg. 3574

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities (see Note 3), and receivables from sanofi-aventis and Bayer HealthCare (see Note 4).

Per Share Data

Net income (loss) per share, basic and diluted, is computed on the basis of the net income (loss) for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock outstanding, and of common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the "treasury stock method" when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's formerly outstanding convertible senior subordinated notes, which are included under the "if-converted method" when dilutive. The computation of diluted net loss per share for the years ended December 31, 2008, 2007, and 2006 does not include common stock equivalents, since such inclusion would be antidilutive.

Risks and Uncertainties

Developing and commercializing new medicines entails significant risk and expense. Since its inception, the Company has not generated any significant sales or profits from the commercialization of ARCALYST® (rilonacept) or any of the Company's other product candidates. Before revenues from the commercialization of the Company's current or future product candidates can be realized, the Company (or its collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render the Company's products and technologies uncompetitive or obsolete. The Company may be subject to legal claims by third parties seeking to enforce patents to limit or prohibit the Company from marketing or selling its products. The Company is also dependent upon the services of its employees, consultants, collaborators, and certain third-party suppliers, including single-source unaffiliated third-party suppliers of certain raw materials and equipment. Regeneron, as licensee, licenses certain technologies that are important to the Company's business which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate the Company's licenses.

The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) up-front, license, milestone, and reimbursement payments from the Company's collaborators and other entities related to the Company's development activities and technology platforms, (ii) payments for past contract manufacturing activities, (iii) ARCALYST product sales, and (iv) investment income. Contract research and development revenue in 2008 was primarily earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 10 for the terms of these agreements). These collaboration agreements contain early termination provisions that are exercisable by sanofi-aventis or Bayer HealthCare, as applicable.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Estimates which could have a significant impact on the Company's financial statements include:

- Periods over which payments, including non-refundable up-front, license, and milestone payments, are recognized as revenue in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3575

Samsung Bioepis Exhibit 1017, pg. 3575

- Product rebates and returns in connection with the recognition of revenue from product sales.

- Periods over which certain clinical trial costs, including costs for clinical activities performed by contract research organizations, are recognized as research and development expenses.

- The fair value of stock options on their date of grant using the Black-Scholes option-pricing model, based on assumptions with respect to (a) expected volatility of the Company's Common Stock price, (b) the periods of time for which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (c) expected dividend yield on the Company's Common Stock, and (d) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. In addition, in connection with the recognition of stock-based employee compensation expense, the Company is required to estimate, at the time of grant, the number of stock option awards that are expected to be forfeited.

- The Company's determination of whether marketable securities are other than temporarily impaired. The Company conducts a quarterly review of its portfolio of marketable securities, using both quantitative and qualitative factors, to determine, for securities whose current fair value is less than their cost, whether the decline in fair value below cost is other-than-temporary. In making this determination, the Company considers factors such as the length of time and the extent to which fair value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of the Company's ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.

- Useful lives of property, plant, and equipment.

- The extent to which deferred tax assets and liabilities are offset by a valuation allowance.

Future Impact of Recently Issued Accounting Standards

In November 2007, the Emerging Issues Task Force issued Statement No. 07-1, *Accounting for Collaborative Arrangements* ("EITF 07-1"). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and will be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. The Company is required to adopt EITF 07-1 for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of EITF 07-1 will have a material impact on the Company's financial statements.

In March 2008, the Financial Accounting Standards Board ("FASB") issued SFAS 161, *Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement 133*. SFAS 161 enhances required disclosures regarding derivatives and hedging activities, including enhanced disclosures regarding how (a) an entity uses derivative instruments, (b) derivative instruments and related hedged items are accounted for under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities,* and (c) derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years and interim periods beginning after November 15, 2008. The Company is required to adopt SFAS 161 for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of SFAS 161 will have a material impact on the Company's financial statements.

In April 2008, the FASB issued FASB Staff Position ("FSP") FAS 142-3, *Determination of the Useful Life of Intangible Assets*. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3576

Samsung Bioepis Exhibit 1017, pg. 3576

under SFAS 141R under this and other generally accepted accounting principles ("GAAP"). This FSP is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. The Company is required to adopt FSP FAS 142-3 for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of this FSP will have a material impact on the Company's financial statements.

3. Marketable Securities

Marketable securities at December 31, 2008 and 2007 consisted of debt securities, as detailed below, and, in 2008, equity securities whose fair value was $3.7 million and cost was $4.1 million. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized holding gains and losses on those securities at December 31, 2008 and 2007:

	Amortized	Fair	Unrealized Holding		
At December 31, 2008	Cost Basis	Value	Gains	(Losses)	Net
Maturities within one year					
U.S. government obligations	$ 170,993	$172,253	$1,260		$1,260
Corporate bonds	26,893	26,661	25	$ (257)	(232)
Asset-backed securities	16,939	16,248		(691)	(691)
U.S. government guaranteed collateralized mortgage obligations	11,742	11,792	50		50
	226,567	226,954	1,335	(948)	387
Maturities between one and three years					
U.S. government guaranteed corporate bonds	29,853	29,811	82	(124)	(42)
Corporate bonds	10,446	10,414	77	(109)	(32)
Asset-backed securities	1,821	1,556		(265)	(265)
U.S. government guaranteed collateralized mortgage obligations	5,296	5,569	273		273
	47,416	47,350	432	(498)	(66)
	$ 273,983	$274,304	$1,767	$ (1,446)	$ 321
At December 31, 2007					
Maturities within one year					
U.S. government obligations	$ 50,386	$ 50,475	$ 89		$ 89
Corporate and municipal bonds	69,213	69,263	74	$ (24)	50
Asset-backed securities	32,671	32,388	42	(325)	(283)
U.S. government guaranteed collateralized mortgage obligations	41,268	41,318	57	(7)	50
Commercial paper	64,846	64,870	25	(1)	24
Certificates of deposit	9,220	9,218		(2)	(2)
	267,604	267,532	287	(359)	(72)
Maturities between one and two years					
Corporate and municipal bonds	49,724	49,947	289	(66)	223
Asset-backed securities	12,949	12,838	34	(145)	(111)
U.S. government guaranteed collateralized mortgage obligations	7,346	7,485	139		139
Commercial paper	7,952	7,952			
	77,971	78,222	462	(211)	251
	$ 345,575	$345,754	$ 749	$ (570)	$ 179

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3577

Samsung Bioepis Exhibit 1017, pg. 3577

At December 31, 2008, marketable securities included an additional unrealized holding loss of $0.4 million related to one equity security in the Company's marketable securities portfolio. At December 31, 2007, cash equivalents included an unrealized holding loss of $9 thousand.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at December 31, 2008 and 2007. The debt securities listed at December 31, 2008 mature at various dates through December 2011.

	Less than 12 Months		12 Months or Greater		Total	
At December 31, 2008	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$15,559	$(287)	$ 2,933	$ (79)	$18,492	$ (366)
Government guaranteed corporate bonds	11,300	(124)			11,300	(124)
Asset-backed securities	8,700	(87)	9,104	(869)	17,804	(956)
Equity securities	3,608	(436)			3,608	(436)
	$39,167	$(934)	$12,037	$(948)	$51,204	$(1,882)
At December 31, 2007						
Corporate and municipal bonds	$36,979	$ (89)	$ 3,056	$ (1)	$40,035	$ (90)
Asset backed securities	18,674	(360)	5,566	(109)	24,240	(469)
U.S. government guaranteed collateralized mortgage obligation			6,824	(7)	6,824	(7)
Commercial paper	14,950	(2)			14,950	(2)
Certificates of deposit	9,218	(2)			9,218	(2)
	$79,821	$(453)	$15,446	$(117)	$95,267	$ (570)

Realized gains and losses are included as a component of investment income. For the year ended December 31, 2008, realized gains on sales of marketable securities totaled $1.2 million and realized losses on sales of marketable securities were not significant. For the years ended December 31, 2007 and 2006, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The Company adopted the provisions of SFAS 157 for financial instruments as of January 1, 2008. Although the adoption of SFAS 157 did not materially impact the Company's financial condition, results of operations, or cash flows, the Company is now required to provide additional disclosures as part of its financial statements. In addition, in October 2008, the FASB issued FSP 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active,* which clarifies the application of SFAS 157 in a market that is not active. FSP 157-3 also reaffirms the notion of fair value as an exit price as of the measurement date. FSP 157-3 was effective upon issuance for financial statements that had not yet been issued and adopted by the Company for the year ended December 31, 2008.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers are Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3578

Samsung Bioepis Exhibit 1017, pg. 3578

The Company's assets that are measured at fair value on a recurring basis, and that are subject to the disclosure requirements of SFAS 157 at December 31, 2008, were as follows:

		Fair Value Measurements at Reporting Date Using		
Description	Fair Value at December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale marketable securities	$278,015	$3,608	$274,307	$100

Marketable securities included in Level 2 above were valued using a market approach utilizing prices and other relevant information generated by market transactions involving identical or comparable assets. During the year ended December 31, 2008, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the security's principal value. As a result, the Company recognized a $1.8 million charge related to this Level 2 marketable security, which the Company considered to be other than temporarily impaired.

Marketable securities included in Level 3 above were valued using information provided by the Company's investment advisors, including quoted bid prices which take into consideration the securities' current lack of liquidity. During the year ended December 31, 2007, deterioration in the credit quality of marketable securities from two issuers subjected the Company to the risk of not being able to recover the full principal value of these securities. As a result, the Company recognized a $5.9 million charge related to these marketable securities, which the Company considered to be other than temporarily impaired. During the year ended December 31, 2008, the Company recognized an additional $0.7 million other-than-temporary impairment charge related to one of these marketable securities.

Changes in marketable securities included in Level 3 above during the twelve month period ended December 31, 2008 were as follows:

	Level 3 Marketable Securities
Balance, January 1, 2008	$7,950
Settlements	(8,194)
Realized gain	1,044
Impairments	(700)
Balance, December 31, 2008	$ 100

There were no unrealized gains or losses related to the Company's Level 3 marketable securities for the year ended December 31, 2008. In addition, there were no purchases of Level 3 marketable securities and no transfers of marketable securities between the Level 2 and Level 3 classifications during the period.

As described in Note 2 above under "Use of Estimates", on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. As a result of these quarterly reviews, in 2008 and 2007, the Company recorded charges for other-than-temporary impairment of its marketable securities totaling $2.5 million and $5.9 million, respectively, as described above, which are included as a component of investment income. However, the current economic environment, the deterioration in the credit quality of some of the issuers of securities that the Company holds, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in the Company's investment portfolio and that such declines could result in additional charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3579

Samsung Bioepis Exhibit 1017, pg. 3579

4. Accounts Receivable

Accounts receivable as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Receivable from sanofi-aventis (see Note 10)	$33,302	$14,244
Receivable from Bayer HealthCare (see Note 10)		2,797
Other	1,910	1,279
	$35,212	$18,320

5. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Land	$ 2,117	$ 2,117
Building and improvements	74,343	66,208
Leasehold improvements	2,720	13,982
Construction-in-progress	24,520	4,677
Laboratory and other equipment	75,935	61,717
Furniture, computer and office equipment, and other	7,501	6,080
	187,136	154,781
Less, accumulated depreciation and amortization	(99,283)	(96,477)
	$ 87,853	$ 58,304

Construction-in-progress at December 31, 2008 included $13.4 million of tenant improvement and equipment costs in connection with the Company's new leased facilities in Tarrytown, New York that are currently under construction. See Note 9a.

Depreciation and amortization expense on property, plant, and equipment amounted to $10.6 million, $10.4 million, and $14.3 million for the years ended December 31, 2008, 2007, and 2006, respectively. Included in these amounts was $0.7 million of depreciation and amortization expense related to contract manufacturing that was capitalized into inventory for the year ended December 31, 2006.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Accounts payable	$ 6,268	$ 8,128
Payable due to Bayer HealthCare (see Note 10)	9,799	4,892
Accrued payroll and related costs	5,948	14,514
Accrued clinical trial expense	4,273	5,609
Accrued expenses, other	9,880	3,797
Interest payable on convertible notes		2,292
	$36,168	$39,232

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3580

Samsung Bioepis Exhibit 1017, pg. 3580

7. Deferred Revenue

Deferred revenue as of December 31, 2008 and 2007 consists of the following:

	2008	2007
Current portion:		
Received from sanofi-aventis (see Note 10)	$ 21,390	$ 18,855
Received from Bayer HealthCare (see Note 10)	9,884	13,179
Received for technology license agreements (see Note 11)	11,579	11,579
Other	4,651	819
	$ 47,504	$ 44,432
Long-term portion:		
Received from sanofi-aventis (see Note 10)	$105,586	$126,431
Received from Bayer HealthCare (see Note 10)	56,835	65,896
	$162,421	$192,327

8. Stockholders Equity

The Company's Restated Certificate of Incorporation provides for the issuance of up to 40 million shares of Class A Stock, par value $0.001 per share, and 160 million shares of Common Stock, par value $0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's board of directors (the "Board") is authorized to issue up to 30 million shares of preferred stock, in series, with rights, privileges, and qualifications of each series determined by the Board.

In November 2006, the Company completed a public offering of 7.6 million shares of Common Stock at a price of $23.03 per share and received proceeds, after expenses, of $174.6 million.

In September 2003, sanofi-aventis purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for $45.0 million. See Note 10.

In December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for an aggregate cash price of $312.0 million. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with the Company. Under the investor agreement, sanofi-aventis has three demand rights to require the Company to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Company's Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the License and Collaboration Agreement under the Company's antibody collaboration with sanofi-aventis (see Note 10) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept (see Note 10), sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of the Company's Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Sanofi-aventis has also agreed not to dispose of any shares of the Company's Common Stock that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2012, subject to certain limited exceptions. Following December 20, 2012, sanofi-aventis will be permitted to sell shares of the Company's Common Stock (i) in a registered underwritten public offering undertaken pursuant to the demand registration rights granted to sanofi-aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of the Company's Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3581

Samsung Bioepis Exhibit 1017, pg. 3581

more of the outstanding shares of the Company's Common Stock, and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by the Company's Board of Directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of the Company's voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by the Company's Board of Directors or proportionally with the votes cast by the Company's other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of the Company's Class A Stock and Common Stock, and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

9. Commitments and Contingencies

a. Operating Leases

The Company currently leases laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, the Company entered into a new operating lease agreement to lease laboratory and office space that is now under construction and expected to be completed in mid-2009 at the Company's current Tarrytown location, plus retain a portion of the Company's existing space. In October 2007 and September 2008, the Company amended the December 2006 operating lease agreement to increase the amount of new and existing space to be leased. The term of the lease commenced effective June 30, 2008 and will expire in June 2024. Under the new lease the Company also has various options and rights on additional space at the Tarrytown site, and will continue to lease its present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for the Company's retained facilities only. The lease provides for monthly payments over the term of the lease related to the Company's retained facilities, the costs of construction and tenant improvements for the Company's new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, the Company issued a letter of credit in the amount of $1.6 million to its landlord, which is collateralized by a $1.6 million bank certificate of deposit. The certificate of deposit has been classified as restricted cash at December 31, 2008 and 2007.

In November 2007, the Company entered into a new operating sublease for additional office space in Tarrytown, New York. The lease expires in September 2009 and contains two renewal options to extend the term of the sublease by three months each. In April 2008, the Company entered into a new operating sublease for additional office space located in Tarrytown, New York. The lease expires in March 2010 and contains one renewal option to extend the term of the sublease by six months. In October 2008 the Company entered into a new sublease with sanofi-aventis U.S. Inc. for office space in Bridgewater, New Jersey. The lease commences in January 2009 and expires in July 2011.

The Company formerly leased manufacturing, office, and warehouse facilities in Rensselaer, New York under an operating lease agreement. The lease provided for base rent plus additional rental charges for utilities, taxes, and operating expenses, as defined. In June 2007, the Company exercised a purchase option under the lease and, in October 2007, purchased the land and building.

The Company leases certain laboratory and office equipment under operating leases which expire at various times through 2011.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3582

Samsung Bioepis Exhibit 1017, pg. 3582

Based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities that are under construction in Tarrytown, New York, as described above, at December 31, 2008, the estimated future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2009	$ 8,707	$419	$ 9,126
2010	13,121	241	13,362
2011	13,252	146	13,398
2012	13,428		13,428
2013	13,764		13,764
Thereafter	166,973		166,973
	$229,245	$806	$230,051

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
2008	$10,111	$416	$10,527
2007	4,632	363	4,995
2006	4,492	307	4,799

As described above, the term of the Company's operating lease for its new facilities in Tarrytown, New York commenced in mid-2008; as a result, the Company began recognizing rent expense in connection with this new lease, even though actual rent payments will not commence until August 2009. In addition to its rent expense for various facilities, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of $8.4 million, $8.8 million, and $8.7 million for the years ended December 31, 2008, 2007, and 2006, respectively.

b. Convertible Debt

In October 2001, the Company issued $200.0 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company of $192.7 million, after deducting the initial purchasers' discount and out-of-pocket expenses (collectively, "Deferred Financing Costs"). The Notes bore interest at 5.5% per annum, payable semi-annually, and matured on October 17, 2008. Deferred Financing Costs, which were included in other assets, were amortized as interest expense over the period from the Notes' issuance to stated maturity. During the second and third quarters of 2008, the Company repurchased $82.5 million in principal amount of the Notes for $83.3 million and recognized a $0.9 million loss on early extinguishment of debt, representing the premium paid on the Notes plus related unamortized Deferred Financing Costs. The remaining $117.5 million of outstanding Notes were repaid in full upon their maturity in October 2008.

c. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with related and unrelated companies, scientific collaborators, universities, and consultants. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company, services to be provided, and ownership rights to certain proprietary technology developed under the agreements. Some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.25% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

Certain agreements under which the Company is required to pay fees permit the Company, upon 30 to 90-day written notice, to terminate such agreements. With respect to payments associated with these agreements, the Company incurred expenses of $3.5 million, $1.0 million, and $1.1 million for the years ended December 31, 2008, 2007, and 2006, respectively.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3583

Samsung Bioepis Exhibit 1017, pg. 3583

In connection with the Company's receipt of marketing approval from the FDA for ARCALYST® (rilonacept) for the treatment of CAPS, in 2008, the Company commenced paying royalties under various licensing agreements based on ARCALYST net product sales. For the year ended December 31, 2008, ARCALYST royalties totaled $0.6 million and are included in cost of goods sold.

In July 2008, the Company and Cellectis S.A. ("Cellectis") entered into an Amended and Restated Non-Exclusive License Agreement (the "Cellectis Agreement"). The Cellectis Agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which the Company licensed certain patents and patent applications from Cellectis. Pursuant to the Cellectis Agreement, in July 2008, the Company made a non-refundable $12.5 million payment to Cellectis (the "Cellectis Payment") and agreed to pay Cellectis a low single-digit royalty based on revenue received by the Company from any future licenses or sales of the Company's *VelociGene*® or *VelocImmune*® products and services. No royalties are payable with respect to the Company's *VelocImmune* license agreements with AstraZeneca UK Limited ("AstraZeneca") and Astellas Pharma Inc. ("Astellas") or the Company's November 2007 collaboration with sanofi-aventis. Moreover, no royalties are payable on any revenue from commercial sales of antibodies from the Company's *VelocImmune* technology.

The Company began amortizing the Cellectis Payment in the second quarter of 2008 in proportion to past and future anticipated revenues under the Company's license agreements with AstraZeneca and Astellas and the Discovery and Preclinical Development Agreement under the Company's November 2007 collaboration with sanofi-aventis. In 2008, the Company recognized $2.7 million of expense in connection with the Cellectis Payment.

10. Research and Development Agreements

The Company has entered into various agreements related to its activities to develop and commercialize product candidates and utilize its technology platforms. Amounts earned by the Company in connection with these agreements, which were recognized as contract research and development revenue, totaled $192.2 million, $96.6 million, and $51.1 million in 2008, 2007, and 2006, respectively. Total Company incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost-sharing of a collaborator's development expenses, where applicable (see Bayer HealthCare below), were $230.6 million, $108.2 million and $43.4 million in 2008, 2007, and 2006, respectively. Significant agreements of this kind are described below.

a. The sanofi-aventis Group

Aflibercept

In September 2003, the Company entered into a collaboration agreement (the "Aventis Agreement") with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.), to jointly develop and commercialize aflibercept. In connection with this agreement, sanofi-aventis made a non-refundable up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for $45.0 million.

In January 2005, the Company and sanofi-aventis amended the Aventis Agreement to exclude intraocular delivery of aflibercept to the eye ("Intraocular Delivery") from joint development under the agreement, and product rights to aflibercept in Intraocular Delivery reverted to Regeneron. In connection with this amendment, sanofi-aventis made a $25.0 million non-refundable payment to Regeneron (the "Intraocular Termination Payment") in January 2005.

In December 2005, the Company and sanofi-aventis amended the Aventis Agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a $25.0 million non-refundable up-front payment to the Company, which was received in January 2006. Under the Aventis Agreement, as amended, the Company and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan, for disease indications included in the companies' collaboration. The Company is entitled to a royalty of approximately 35% on annual sales of aflibercept in Japan, subject to certain potential adjustments. The Company may also receive up to $400 million in milestone

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3584

Samsung Bioepis Exhibit 1017, pg. 3584

payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

Under the Aventis Agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of these development expenses, or half of $446.5 million as of December 31, 2008, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits and Japan royalties, or at a faster rate at Regeneron's option. Regeneron has the option to conduct additional pre-Phase III studies at its own expense. In connection with the January 2005 amendment to the Aventis Agreement, the Intraocular Termination Payment of $25.0 million will be considered an aflibercept development expense and will be subject to 50% reimbursement by Regeneron to sanofi-aventis, as described above, if the collaboration becomes profitable. In addition, if the first commercial sale of an aflibercept product in Intraocular Delivery predates the first commercial sale of an aflibercept product under the collaboration by two years, Regeneron will begin reimbursing sanofi-aventis for up to $7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, Regeneron's obligation to reimburse sanofi-aventis, for 50% of aflibercept development expenses will terminate, and the Company will retain all rights to aflibercept.

Revenue related to payments from sanofi-aventis under the Aventis Agreement, as amended, is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The up-front payments received in September 2003 and January 2006, of $80.0 million and $25.0 million, respectively, and reimbursement of Regeneron-incurred development expenses, are being recognized as contract research and development revenue over the related performance period. The Company recognized $44.4 million, $47.1 million, and $47.8 million of contract research and development revenue in 2008, 2007, and 2006, respectively, in connection with the Aventis Agreement, as amended. At December 31, 2008 and 2007, amounts receivable from sanofi-aventis totaled $6.3 million and $10.5 million, respectively, and deferred revenue was $52.4 million and $61.2 million, respectively, in connection with the Aventis Agreement.

Antibodies

In November 2007, the Company entered into a global, strategic collaboration (the "Antibody Collaboration") with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. In connection with the collaboration, in December 2007, sanofi-aventis purchased 12 million newly issued; unregistered shares of the Company's Common Stock for $312.0 million (see Note 8).

The Antibody Collaboration is governed by a Discovery and Preclinical Development Agreement (the "Discovery Agreement") and a License and Collaboration Agreement (the "License Agreement"). The Company received a non-refundable up-front payment of $85.0 million from sanofi-aventis under the Discovery Agreement. In addition, sanofi-aventis will fund up to $475 million of the Company's research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against such targets through December 31, 2012, subject to specified funding limits of $75 million for the period from the collaboration's inception through December 31, 2008, and $100 million annually in each of the next four years. The Discovery Agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the Discovery Agreement, sanofi-aventis has the option to license rights to the candidate under the License Agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with the Company through product approval. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the License Agreement, the Company will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The first three therapeutic antibodies that are being co-developed by the Company and sanofi-aventis under the License Agreement are REGN88, REGN421, and REGN475.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3585

Samsung Bioepis Exhibit 1017, pg. 3585

Under the License Agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") will be shared 80% by sanofi-aventis and 20% by Regeneron. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of $27.8 million as of December 31, 2008) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products.

Sanofi-aventis will lead commercialization activities for products developed under the License Agreement, subject to the Company's right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (Regeneron) and ending at 55% (sanofi-aventis)/45% (Regeneron), and losses outside the United States at 55% (sanofi-aventis)/45% (Regeneron). In addition to profit sharing, the Company is entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured.

With respect to each antibody product which enters development under the License Agreement, sanofi-aventis or the Company may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. The Company may also opt-out of the further development of an antibody product if it gives notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the License Agreement. Each of the Discovery Agreement and the License Agreement contains other termination provisions, including for material breach by the other party and, in the case of the Discovery Agreement, a termination right for sanofi-aventis under certain circumstances, including if certain minimal criteria for the discovery program are not achieved. Prior to December 31, 2012, sanofi-aventis has the right to terminate the Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to the Company the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate. Upon expiration of the Discovery Agreement, sanofi-aventis has an option to license the Company's *VelocImmune*® technology for agreed upon consideration.

In connection with the Antibody Collaboration, in August 2008, the Company entered into a separate agreement with sanofi-aventis to use Regeneron's proprietary *VelociGene*® technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease (the "*VelociGene* Agreement"). The VelociGene Agreement provides for minimum annual order quantities for the term of the agreement which extends through December 2012, for which the Company expects to receive payments totaling a minimum of $21.5 million.

Revenue related to payments from sanofi-aventis under the Antibody Collaboration is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The (i) $85.0 million up-front payment received in December 2007, (ii) reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements, and (iii) $21.5 million of aggregate minimum payments under the *VelociGene* Agreement are being recognized as contract research and development revenue over the related performance period. In connection with the Antibody Collaboration, the Company recognized $109.6 million and $4.6 million of contract research and development revenue in 2008 and 2007, respectively. In addition, at December 31, 2008 and 2007, amounts receivable from sanofi-aventis totaled $27.0 million and $3.7 million and deferred revenue was $74.6 million and $84.1 million, respectively.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3586

Samsung Bioepis Exhibit 1017, pg. 3586

b. Bayer HealthCare LLC

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to the Company of $75.0 million. In addition, the Company is eligible to receive up to $110 million in development and regulatory milestones related to the VEGF Trap-Eye program, of which the Company received a $20.0 million milestone payment in August 2007 in connection with the initiation of a Phase 3 trial of VEGF Trap-Eye in the neovascular form of age-related macular degeneration ("wet AMD"). The Company is also eligible to receive up to an additional $135 million in sales milestones when and if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer HealthCare out of its share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of $63.0 million as of December 31, 2008) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. Within the United States, the Company is responsible for any future commercialization of VEGF Trap-Eye and retains exclusive rights to any future profits from commercialization.

Agreed upon VEGF Trap-Eye development expenses incurred by both companies in 2007 and 2008 under a global development plan, were shared as follows:

2007: The first $50.0 million was shared equally and the Company was solely responsible for up to the next $40.0 million.

2008: The first $70.0 million was shared equally and the Company was solely responsible for up to the next $30.0 million.

In 2009 and thereafter, all development expenses will be shared equally. Neither party was reimbursed for any development expenses that it incurred prior to 2007. The Company is also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

Bayer HealthCare has the right to terminate the Bayer Agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to VEGF Trap-Eye.

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue for financial statement purposes. In the fourth quarter of 2007, Regeneron and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps, timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. In addition, in the fourth quarter of 2007, Regeneron and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's VEGF Trap-Eye development expenses. The $75.0 million up-front licensing payment and $20.0 million milestone payment (which was not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue over the related estimated performance period in accordance with SAB 104 and EITF 00-21 (see Note 2). In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3587

Samsung Bioepis Exhibit 1017, pg. 3587

the Company also recognizes, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse. In the fourth quarter of 2007, the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

In 2008, the Company recognized $31.2 million of contract research and development revenue from Bayer HealthCare, consisting of $12.4 million related to the up-front licensing and milestone payments and $18.8 million related to the portion of the Company's 2008 VEGF Trap-Eye development expenses that was reimbursable from Bayer HealthCare. In 2007, the Company recognized $35.9 million of contract research and development revenue from Bayer HealthCare, consisting of $15.9 million related to the up-front licensing and milestone payments and $20.0 million related to the portion of the Company's 2007 VEGF Trap-Eye development expenses that was reimbursable from Bayer HealthCare. In addition, in 2008 and 2007, the Company recognized as additional research and development expense $30.0 million and $10.6 million, respectively, of VEGF Trap-Eye development expenses that the Company was obligated to reimburse to Bayer HealthCare.

In connection with cost-sharing of VEGF Trap-Eye development expenses under the collaboration, $9.8 million and $4.9 million was payable to Bayer HealthCare at December 31, 2008 and 2007, respectively, and $2.8 million was receivable from Bayer HealthCare at December 31, 2007. In addition, at December 31, 2008 and 2007, deferred revenue from the Company's collaboration with Bayer HealthCare was $66.7 million and $79.1 million, respectively.

c. Serono, S.A. (now part of Merck KGaA)

In December 2002, the Company entered into an agreement (the "Serono Agreement") with Serono S.A. to use Regeneron's proprietary *VelociGene*® technology platform to provide Serono with knock-out and transgenic mammalian models of gene function ("Materials"). The Serono Agreement contains provisions for minimum yearly order quantities. In connection with its orders for Materials, Serono makes advance payments to Regeneron, which are accounted for as deferred revenue. Regeneron recognizes revenue and reduces the deferred revenue balance as Materials are shipped to and accepted by Serono. In 2008, 2007, and 2006, the Company recognized $0.9 million, $2.4 million, and $1.8 million, respectively, of contract research and development revenue in connection with the Serono Agreement.

d. National Institutes of Health

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. As amended, the NIH grant provides a minimum of $24.5 million in funding over a five-year period, including $1.5 million in funding to optimize certain existing technology, subject to compliance with its terms and annual funding approvals, for the Company's use of its *VelociGene* technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells which can be used to produce knockout mice. In 2008, 2007, and 2006, the Company recognized contract research and development revenue of $4.9 million, $5.5 million, and $0.5 million, respectively, from the NIH Grant.

11. Technology Licensing Agreements

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made two $20.0 million annual, non-refundable payments to the Company, one in 2007 and the other in 2008. Each annual payment is deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. AstraZeneca is required to make up to four additional annual payments of $20.0 million, subject to their ability to terminate the agreement after making two such additional payments or earlier if the technology does not meet minimum performance criteria. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's *VelocImmune* technology. In connection with the AstraZeneca license agreement, for the years ended December 31, 2008 and 2007, the Company recognized $20.0 million and $17.1 million of revenue. In addition, deferred revenue at both December 31, 2008 and 2007 was $2.9 million.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3588

Samsung Bioepis Exhibit 1017, pg. 3588

In March 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made two $20.0 million annual, non-refundable payments to the Company, one in 2007 and the other in 2008. Each annual payment is deferred and, recognized as revenue ratably over approximately the ensuing twelve-month period. Astellas is required to make up to four additional annual payments of $20.0 million, subject to their ability to terminate the agreement after making two such additional payments or earlier if the technology does not meet minimum performance criteria. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune* technology. In connection with the Astellas license agreement, for the years ended December 31, 2008 and 2007, the Company recognized $20.0 million and $11.3 million of revenue. In addition, deferred revenue at both December 31, 2008 and 2007 was $8.7 million.

12. Manufacturing Agreement

During 1995, the Company entered into a long-term manufacturing agreement with Merck & Co., Inc., as amended, (the "Merck Agreement") to produce an intermediate (the "Intermediate") for a Merck pediatric vaccine at the Company's Rensselaer, New York facility. The Company modified portions of its facility for manufacture of the Intermediate and assisted Merck in securing regulatory approval for such manufacture in the Company's facility. The Merck Agreement called for the Company to manufacture Intermediate for Merck for a specified period of time (the "Production Period"), with certain minimum order quantities each year. The Production Period commenced in November of 1999 and, as amended, extended through October 2006, at which time the Merck Agreement terminated.

Merck agreed to reimburse the Company for the capital costs to modify the facility ("Capital Costs"). Merck also agreed to pay an annual facility fee (the "Facility Fee") of $1.0 million beginning March 1995, subject to annual adjustment for inflation. During the Production Period, Merck agreed to reimburse the Company for certain manufacturing costs, pay the Company a variable fee based on the quantity of Intermediate supplied to Merck, and make additional bi-annual payments ("Additional Payments"), as defined. In addition, Merck agreed to reimburse the Company for miscellaneous costs during the Production Period ("Internal Costs"). These payments were recognized as contract manufacturing revenue as follows: (i) payments for Internal Costs were recognized as the activities were performed, (ii) the Facility Fee and Additional Payments were recognized over the period to which they related, (iii) payments for Capital Costs were deferred and recognized as Intermediate was shipped to Merck, and (iv) payments related to the manufacture of Intermediate during the Production Period were recognized after the Intermediate was tested and approved by, and shipped (FOB shipping point) to, Merck. In 2006, Merck contract manufacturing revenue totaled $12.3 million, which included $1.2 million of previously deferred Capital Costs.

13. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. For the year-ended December 31, 2008, the Company recognized as revenue $6.3 million of ARCALYST net product sales for which the right of return no longer existed and rebates could be reasonably estimated. At December 31, 2008, deferred revenue related to ARCALYST net product sales totaled $4.0 million.

Cost of goods sold related to ARCALYST sales totaled $0.9 million for the year ended December 31, 2008 and consisted primarily of royalties (see Note 9c). In 2008, ARCALYST shipments to the Company's customers consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST; therefore, the costs of these supplies were not included in costs of goods sold. At December 31, 2008, the Company had no inventoried costs related to ARCALYST.

14. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan which, as amended and restated (the "2000 Incentive Plan"), provides for the issuance of up to 28,816,184 shares of Common Stock in respect of awards. In addition, shares of Common Stock previously approved by shareholders for

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3589

Samsung Bioepis Exhibit 1017, pg. 3589

issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant. The maximum term of options that have been awarded under the 2000 Incentive Plan is ten years.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the Restricted Stock, which has not vested, will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts, if any, paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

Phantom Stock awards provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of the Company's Common Stock as determined by the Committee, equal to the sum of the fair market value of a share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests. Stock Bonus awards are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Company's Common Stock. Subject to the provisions of the 2000 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

During 1990, the Company established the 1990 Incentive Plan which, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, received awards as determined by a committee of independent directors. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. Awards under the 1990 Incentive Plan consisted of Incentive Stock Options and Nonqualified Stock Options which generally vested on a pro rata basis over a three or five year period and have a term of ten years.

The 1990 and 2000 Incentive Plans contain provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined.

As of December 31, 2008, there were 6,912,833 shares available for future grants under the 2000 Incentive Plan.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3590

Samsung Bioepis Exhibit 1017, pg. 3590

a. Stock Options

Transactions involving stock option awards during 2006, 2007, and 2008 under the 1990 and 2000 Incentive Plans are summarized in the table below.

Stock Options:	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Intrinsic Value (in thousands)
Outstanding at December 31, 2005	14,719,492	$14.23		
2006: Granted	2,742,260	$19.59		
Forfeited	(338,122)	$10.51		
Expired	(172,218)	$24.23		
Exercised	(1,408,907)	$ 9.84		
Outstanding at December 31, 2006	15,542,505	$15.54		
2007: Granted	3,415,743	$21.78		
Forfeited	(220,342)	$14.43		
Expired	(50,759)	$13.73		
Exercised	(1,014,791)	$10.58		
Outstanding at December 31, 2007	17,672,356	$17.05		
2008: Granted	4,126,600	$17.38		
Forfeited	(515,298)	$16.58		
Expired	(34,242)	$26.81		
Exercised	(1,115,906)	$ 9.61		
Outstanding at December 31, 2008	20,133,910	$17.53	6.62	$59,268
Vested and expected to vest at December 31, 2008	19,596,843	$17.52	6.57	$58,394
Exercisable at December 31, 2006	7,890,856	$17.41		
Exercisable at December 31, 2007	9,369,665	$17.02		
Exercisable at December 31, 2008	10,994,371	$17.43	5.08	$42,791

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2008, 2007, and 2006 was $11.9 million, $12.6 million, and $13.2 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The Company grants stock options with exercise prices that are equal to or greater than the market price of the Company's Common Stock on the date of grant. The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2006, 2007, and 2008. The fair value of each option granted under the 2000 Incentive Plan during 2008, 2007, and 2006 was estimated on the date of grant using the Black-Scholes option-pricing model.

	Number of Options Granted	Weighted-Average Exercise Price	Weighted-Average Fair Value
2006:			
Exercise price equal to market price	2,742,260	$19.59	$12.82
2007:			
Exercise price equal to market price	3,415,743	$21.78	$11.13
2008:			
Exercise price equal to market price	4,126,600	$17.38	$ 8.45

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3591

Samsung Bioepis Exhibit 1017, pg. 3591

The following table summarizes stock option information as of December 31, 2008:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$4.83 to $9.49	3,721,142	4.02	$ 8.95	2,815,152	$ 9.10
$9.53 to $13.00	3,588,129	5.93	$12.25	3,069,391	$12.36
$13.05 to $16.80	3,832,641	9.57	$16.53	287,491	$15.26
$17.33 to $20.32	3,508,707	6.95	$19.90	2,076,331	$19.85
$20.37 to $22.12	3,193,837	8.91	$21.68	752,577	$21.79
$22.25 to $37.94	2,229,454	3.38	$31.41	1,933,429	$32.56
$51.56 to $51.56	60,000	1.16	$51.56	60,000	$51.56
$4.83 to $51.56	20,133,910	6.62	$17.53	10,994,371	$17.43

For the years ended December 31, 2008, 2007, and 2006, $30.3 million, $28.0 million, and $18.4 million, respectively, of non-cash stock-based employee compensation expense related to stock option awards was recognized in operating expenses. As of December 31, 2008, there was $46.3 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 2.0 years. In addition, there were 1,302,260 performance-based options which were unvested as of December 31, 2008 of which, subject to the optionee satisfying certain service conditions, 664,760 options would vest upon achieving certain defined sales targets for the Company's products and 637,500 options would vest upon achieving certain development milestones for the Company's product candidates. Potential compensation cost, measured on the grant date, related to these performance options totals $9.1 million and will begin to be recognized only if, and when, these options' performance conditions are considered to be probable of attainment.

Fair value Assumptions:

Using the Black-Scholes option-pricing model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with previously issued employee and board of director option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2008, 2007, and 2006.

	2008	2007	2006
Expected volatility	53%	53%	67%
Expected lives from grant date	5.5 years	5.6 years	6.5 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	1.73%	3.60%	4.51%

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3592

Samsung Bioepis Exhibit 1017, pg. 3592

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the years ended December 31, 2006, 2007, and 2008 is summarized below:

Restricted Stock:	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2005	93,188	$11.16
2006: Forfeited	(1,703)	$ 9.74
Released	(93,485)	$11.18
Outstanding at December 31, 2006	—	
2007: Granted	500,000	$21.92
Outstanding at December 31, 2007	500,000	$21.92
2008: Outstanding at December 31, 2008	500,000	$21.92

In December 2007, the Company awarded a grant of Restricted Stock to the Company's executive vice president. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to grants of Restricted Stock awards. This amount is based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restriction on these shares lapse, which is five years for the grant made in 2007. In addition, unearned compensation in Stockholders' Equity is reduced due to forfeitures of Restricted Stock resulting from employee terminations. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation is combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

In connection with the 2007 grant of Restricted Stock, the Company recorded unearned compensation in Stockholders' Equity of $11.0 million, which was combined with additional paid-in capital. In connection with forfeitures of past Restricted Stock awards, the Company reduced unearned compensation by $17 thousand in 2006. The Company recognized non-cash stock-based employee compensation expense from Restricted Stock awards of $2.2 million, $0.1 million, and $0.3 million in 2008, 2007, and 2006, respectively. As of December 31, 2008, there were 500,000 unvested shares of Restricted Stock outstanding and $8.7 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 4.0 years.

15. Executive Stock Purchase Plan

In 1989, the Company adopted an Executive Stock Purchase Plan (the "Plan") under which 1,027,500 shares of Class A Stock were reserved for restricted stock awards. The Plan provides for the compensation committee of the board of directors to award employees, directors, consultants, and other individuals ("Plan participants") who render service to the Company the right to purchase Class A Stock at a price set by the compensation committee. The Plan provides for the vesting of shares as determined by the compensation committee and, should the Company's relationship with a Plan participant terminate before all shares are vested, unvested shares will be repurchased by the Company at a price per share equal to the original amount paid by the Plan participant. During 1989 and 1990, a total of 983,254 shares were issued, all of which vested as of December 31, 1999. As of December 31, 2008, there were 44,246 shares available for future grants under the Plan.

16. Employee Savings Plan

In 1993, the Company adopted the provisions of the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan provide for employees who have met defined service requirements to participate in the Savings Plan by electing to contribute to the Savings Plan a percentage of their compensation to be set aside to pay their future retirement benefits, as defined. The Savings Plan, as amended and restated, provides for

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3593

Samsung Bioepis Exhibit 1017, pg. 3593

the Company to make discretionary contributions ("Contribution"), as defined. The Company recorded Contribution expense of $1.5 million in 2008, $1.4 million in 2007, and $1.3 million in 2006; such amounts were accrued as liabilities at December 31, 2008, 2007, and 2006, respectively. During the first quarter of 2009, 2008, and 2007, the Company contributed 81,086, 58,575, and 64,532 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

17. Income Taxes

For the year ended December 31, 2008, the Company incurred a net loss for tax purposes and recognized a full tax valuation against deferred taxes. During 2008, the Company implemented a tax planning strategy to utilize net operating loss carry-forwards (which were otherwise due to expire in 2008 through 2012) on its 2007 U.S. federal and New York State income tax returns that were filed in September 2008. The tax planning strategy included electing, for tax purposes only, to capitalize $142.1 million of 2007 research and development ("R&D") costs and amortize these costs over ten years for tax purposes. By capitalizing these R&D costs, the Company was able to generate taxable income for tax year 2007 and utilize the net operating loss carry-forwards to offset this taxable income. As a result, the Company incurred and paid income tax expense of $3.1 million in 2008, which related to U.S. federal and New York State alternative minimum tax ("AMT") and included $0.2 million of interest and penalties. This expense was partly offset by the Company's recognition of a $0.7 million income tax benefit for the year ended December 31, 2008, resulting from a provision in the Housing Assistance Tax Act of 2008 that allows the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2008 U.S federal income tax return.

For the year ended December 31, 2007, the Company had projected to incur a net loss for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes was recorded in 2007. Subsequently, the Company implemented the tax planning strategy described above, which resulted in taxable income in 2007 on which the Company recognized and paid U.S. federal and New York State AMT in 2008. For the year ended December 31, 2006, the Company incurred a net loss for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes was recorded in 2006.

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2008 and 2007 is as follows:

	2008	2007
Deferred tax assets:		
Net operating loss carry-forward	$ 161,790	$ 166,714
Fixed assets	18,612	17,245
Deferred revenue	85,251	96,148
Deferred compensation	22,942	15,159
Research and experimental tax credit carry-forward	22,295	25,446
Capitalized research and development costs	59,661	15,236
Other	9,825	7,036
Valuation allowance	(380,376)	(342,984)
	—	—

The Company's valuation allowance increased by $37.4 million in 2008, due primarily to the increase in the temporary difference related to capitalized research and development costs, resulting from the implementation of the tax planning strategy described above. In 2007, the Company's valuation allowance increased by $30.7 million, due primarily to the temporary difference related to deferred revenue, principally resulting from the non-refundable, up-front payment received from sanofi-aventis in December 2007 (see Note 10).

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*. The implementation of FIN 48 had no impact on the Company's financial statements as the Company has not recognized any income tax positions that were deemed uncertain under the recognition thresholds and measurement attributes prescribed by FIN 48.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3594

Samsung Bioepis Exhibit 1017, pg. 3594

The Company is primarily subject to U.S. federal and New York State income tax. The Company's effective income tax rate is generally zero for all years presented. The difference between the Company's effective income tax rate and the U.S federal statutory rate of 35% is attributable to state tax benefits and tax credit carry-forwards offset by an increase in the deferred tax valuation allowance. The Company's 1998 and subsequent tax years remain open to examination by U.S. federal and state tax authorities.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2008 and 2007, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2008, the Company had available for tax purposes unused net operating loss carry-forwards of $415.4 million which will expire in various years from 2018 to 2028 and included $17.0 million of net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of Incentive Stock Options, the tax benefit from which, if realized, will be credited to additional paid-in capital. The Company's research and experimental tax credit carry-forwards expire in various years from 2009 to 2028. Under the Internal Revenue Code and similar state provisions, substantial changes in the Company's ownership have resulted in an annual limitation on the amount of net operating loss and tax credit carry-forwards that can be utilized in future years to offset future taxable income. This annual limitation may result in the expiration of net operating losses and tax credit carry-forwards before utilization.

18. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition. Legal costs associated with the Company's resolution of legal proceedings are expensed as incurred.

19. Net Loss Per Share Data

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. In 2008, 2007, and 2006, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	December 31,		
	2008	2007	2006
Net loss (Numerator)	$(82,710)	$(105,600)	$(102,337)
Weighted-average shares, in thousands (Denominator)	78,827	66,334	57,970
Basic and diluted net loss per share	$ (1.05)	$ (1.59)	$ (1.77)

Shares issuable upon the exercise of options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the diluted per share amounts because their effect would have been antidilutive, include the following:

	December 31,		
	2008	2007	2006
Options:			
Weighted average number, in thousands	17,598	15,385	14,139
Weighted average exercise price	$ 17.31	$ 15.97	$ 14.41
Restricted Stock:			
Weighted average number, in thousands	500	21	23
Convertible Debt:			
Weighted average number, in thousands		6,611	6,611
Conversion price		$ 30.25	$ 30.25

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3595

Samsung Bioepis Exhibit 1017, pg. 3595

20. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at December 31, 2008, 2007, and 2006 were $7.0 million, $1.7 million, and $0.8 million of accrued capital expenditures, respectively.

Included in accounts payable and accrued expenses at December 31, 2007, 2006, and 2005 were $1.1 million, $1.4 million, and $1.9 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2008, 2007, and 2006, the Company contributed 58,575, 64,532, and 120,960 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at December 31, 2008, 2007, and 2006 were $1.7 million, $2.2 million, and $1.5 million of accrued interest income, respectively.

21. Segment Information

In 2008 and 2007, the Company managed its business as one segment which included all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. This segment also included revenues and expenses related to (i) research and development activities conducted under the Company's collaboration agreements with third parties and the Company's grant from the NIH, (ii) ARCALYST® (rilonacept) product sales for the treatment of CAPS, and (iii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology. In 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing; therefore, segment information has only been provided for 2006 in the table below. In 2006, the contract manufacturing segment included all revenues and expenses related to the commercial production of a product under a contract with Merck, which expired in October 2006. The accounting policies for the segments are the same as those described above in Summary of Significant Accounting Policies.

The following table presents information about reported segments for the year ended December 31, 2006.

2006	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 51,136	$ 12,311	—	$ 63,447
Depreciation and amortization	13,549	—[1]	$ 1,043	14,592
Non-cash compensation expense	18,357	318	(813)[2]	17,862
Interest expense	—	—	12,043	12,043
Net income (loss)	(111,820)	4,165	5,318[3]	(102,337)
Capital expenditures	3,339	—	—	3,339
Total assets	56,843	3	528,244[4]	585,090

(1) Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

(2) Represents the cumulative effect of adopting SFAS 123R.

(3) Represents investment income net of interest expense related to convertible notes issued in October 2001 (see Note 9). For the year ended December 31, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 2).

(4) Includes cash and cash equivalents, marketable securities, restricted cash (where applicable), prepaid expenses and other current assets, and other assets.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3596

Samsung Bioepis Exhibit 1017, pg. 3596

22. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2008 and 2007 are set forth in the following tables.

	First Quarter Ended March 31, 2008	Second Quarter Ended June 30, 2008	Third Quarter Ended September 30, 2008	Fourth Quarter Ended December 31, 2008
			(Unaudited)	
Revenues	$ 56,383	$ 60,653	$ 65,584	$ 55,837
Net loss	(11,618)	(18,459)	(21,115)	(31,518)
Net loss per share, basic and diluted	$ (0.15)	$ (0.23)	$ (0.27)	$ (0.40)

	First Quarter Ended March 31, 2007	Second Quarter Ended June 30, 2007	Third Quarter Ended September 30, 2007	Fourth Quarter Ended December 31, 2007[1]
			(Unaudited)	
Revenues	$ 15,788	$ 22,195	$ 22,311	$ 64,730
Net loss	(29,917)	(26,774)	(35,838)	(13,071)
Net loss per share, basic and diluted	$ (0.46)	$ (0.41)	$ (0.54)	$ (0.19)

(1) As described above in Note 10, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. As a result, in the fourth quarter of 2007, when the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, the Company recognized contract research and development revenue from Bayer HealthCare of $35.9 million and additional research and development expense of $10.6 million.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3597

Samsung Bioepis Exhibit 1017, pg. 3597

As of November 14, 2008

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer,
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591-6707

Dear Len:

This employment agreement will replace and update the agreement dated December 20, 2002 between Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") and you. The compensation obligations of the Company under this agreement (the "Agreement") will be reduced by any amounts actually paid by any affiliate, subsidiary, and related entity controlled by or under common control with the Company ("Related Entity").

1. Employment.

(a) You will continue to serve, during the Employment Term, as President and Chief Executive Officer of the Company with the customary responsibilities and authority of such positions and in accordance with the Company's By-Laws. You will report directly and only to the Board of Directors. If elected, you will also continue to serve as a Director of the Company. The Company shall during the Employment Term recommend and propose you as a Director of the Company and any Related Entity and, if the Chairman of the Board of Directors as of the date hereof at any time ceases to serve as such, as Chairman of the Board of Directors. To the extent you are not elected Chief Executive Officer of any Related Entity, such Chief Executive Officer shall report to you.

(b) During the Employment Term, you shall devote substantially all of your business time and attention to the performance of your duties for the Company and serve the Company diligently and to the best of your ability. You may, however, perform teaching, consulting, patient care, and other activities as you have done from time to time in the past, provided that they do not materially conflict with the performance of your duties to the Company. In addition, you may manage your personal investments and be involved in civic and charitable activities so long as such activities do not materially interfere with your providing services hereunder. During the Employment Term, you shall not serve as a member of a board of directors of any other for-profit corporation (other than a Related Entity) without the prior written consent of the Board of Directors (which consent shall not be unreasonably withheld). In no event will the provisions of this Agreement in any way modify, alter, reduce, or limit the fiduciary obligations you owe to the Company as an officer and Director of the Company.

2. Term. Except for earlier termination as provided in paragraph 4 hereof, your employment under this Agreement (the "Employment Term") is for an initial term that commenced on February 12, 1998 and ended on December 31, 2003 (the "Initial Term") and automatically extended since then. Unless notice is given of an intent not to extend the Initial Term or any extension thereof, by you or by the Company by written notice at least ninety (90) days prior to each December 31 during the Employment Term, the Employment Term shall be deemed as of such 90th day to have been extended and continue until the end of the following calendar year unless otherwise terminated as provided in paragraph 4 hereof.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3598

Samsung Bioepis Exhibit 1017, pg. 3598

3. Compensation/Benefits.

(a) During the Employment Term, you have received base salary at an annual rate of not less than $575,000, paid currently at periodic intervals in accordance with the Company's payroll practices for salaried employees. Adjustments in your base salary during the term of this Agreement (which shall thereafter be your "Base Salary") have been and may be effected from time to time upon the recommendation of the Compensation Committee and the approval of the Board of Directors based upon an annual review by the Compensation Committee, but your Base Salary, once increased, shall in no event be decreased; provided, however, that in the event there is a general reduction of compensation applicable to senior executives generally, nothing herein shall preclude the Board of Director's ability to reduce your Base Salary consistent with this reduction. You shall also participate in and be the beneficiary of any cash bonus payments, stock option and other equity programs, incentive programs, pension plans, profit sharing plans and other benefit programs and fringe benefit programs implemented by the Company and otherwise available to executive officers, nonindependent directors, and employees of the Company, at a level commensurate with your position, in accordance with the terms and conditions of such programs.

(b) You have separately entered into one or more stock purchase agreements and stock option award agreements with the Company. With the sole exception of the provisions in this Agreement regarding vesting and exercisability of stock options, nothing in this Agreement will affect any term or provision of any stock purchase or stock option award agreement you have entered into or will enter into with the Company under any stock purchase or incentive plan of the Company and the stock options to purchase common shares previously granted to you shall remain outstanding, and in effect, in accordance with their respective terms.

(c) The Company will during the Employment Term maintain insurance on your life in the amount of $1,000,000 payable to such beneficiary as you designate. You may change the designated beneficiary of this policy at any time. The Company will not borrow against or otherwise encumber the policy or proceeds thereof. The Company will also during the Employment Term maintain for your benefit a long term disability policy that will pay you at least 65 percent of your Base Salary during such period as you are unable, for physical or mental reasons, to perform the responsibilities of your current position, with such benefits commencing no later than six (6) months after incurrence of the disability.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3599

Samsung Bioepis Exhibit 1017, pg. 3599

(d) During the Employment Term, subject to paragraph 14(o)(i), the Company will pay for or will reimburse the reasonable costs of your medical malpractice insurance and all customary, ordinary, and necessary business expenses incurred by you in the performance of your duties (including expenses related to equipment you customarily and normally use in connection with the performance of your duties to the Company), provided that you present such vouchers, receipts, or other documentation as are required by the regular procedures of the Company for the reimbursement of such expenses. In addition, during the Employment Term, the Company will pay you a monthly automobile cash allowance of $1,500 plus all expenses of maintaining and operating your automobile in accordance with current policy.

(e) You shall be entitled to at least four (4) weeks of vacation per year, which vacation may be taken at such times as you elect with due regard to the needs of the Company.

(f) Subject to paragraph 14(o)(i), the Company will pay, or will reimburse the reasonable costs of any legal, accounting or other professional services you incur in connection with your tax preparation and financial planning to an annual maximum of (i) the amount for financial planning and similar benefits generally made available to other senior executives of the Company for such year, plus (ii) $12,500 per year (together, the "Maximum Annual Professional Services Reimbursement Amount"), including, without limitation, a tax gross-up reimbursement, so long as the total direct reimbursement and tax gross-up reimbursement is no more than the Maximum Annual Professional Services Reimbursement Amount per year. For calendar years commencing after December 31, 2004, any accrued unused amount that would have been reimbursed under this paragraph 3(f) during such year will be forfeited to the extent reimbursable expenses are not incurred during the applicable year. For calendar years prior to 2004, any unused amounts under the annual reimbursable cap (the "Grandfathered Reimbursements") under this Agreement and the February 12, 1998 agreement between you and the Company shall continue to be available to you for reimbursement of legal, accounting or other professional service expenses (and tax gross ups) you incur in connection with your tax preparation and financial planning under the terms of this Section 3(f). For the avoidance of doubt, all reimbursements shall first be deemed to come from the annual allowance that, if unused, is subject to forfeiture.

(g) During the Employment Term (and, subject to the terms of this paragraph, thereafter), the Company will continue to designate you as its nominee at the club at which you are currently designated as the nominee of the Company (the "Club") and, subject to paragraph 14(o)(i), pay any dues or other expenses incurred with regard to your use of the Club. After your termination of employment with the Company, you shall, at your election made to the Company within 45 days thereafter: (i) elect not to be designated by the Company as the nominee for the Company's Club membership; (ii) if permitted by the Club, have the Company transfer the Company's Club membership to you, with the Company having its bond either returned or assumed by you (in which case you would pay the Club any dues or other Club expenses incurred thereafter and, if you assumed the bond, would pay the Company the amount of the bond); or (iii) have the Company continue your designation as nominee for the Company's Club membership (in which case you would pay the dues and other Club expenses incurred thereafter and deposit the amount of the Club bond with the Company, with such amount (as adjusted in the same manner as the bond) returned to you by the Company at the earlier of such time as it receives a refund of the bond or you elect to cease being designated as the Company's nominee at the Club). Notwithstanding anything else herein, this obligation shall survive any termination of your employment with the Company.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3600

Samsung Bioepis Exhibit 1017, pg. 3600

(h) Following any termination of your employment with the Company, if and to the extent the Company maintains any health benefit plans (and without any obligation to do so), you and your (and, after your death, your wife's) dependents shall be entitled to continue to participate therein by paying an amount equal to the COBRA cost thereof for the remainder of your life and that of your spouse at the time of such termination of employment. Notwithstanding anything else herein, this provision shall survive any termination of your employment with the Company.

4. Termination. Except as otherwise provided in paragraph 2, the Employment Term shall end upon the earliest of the following to occur:

(a) Your death.

(b) Upon a vote of the Board of Directors and notice to you of termination as a result of your Permanent Disability. Permanent Disability means your inability, by reason of any physical or mental impairment, to substantially perform the significant aspects of your regular duties as contemplated by this Agreement and which inability is reasonably contemplated to continue for at least one (1) year from its incurrence and at least ninety (90) days from the date of such vote. Any question as to the existence, extent, or potentiality of your Permanent Disability shall be determined by a qualified independent physician selected by you (or, if you are unable to make such selection, by an adult member of your immediate family), and reasonably acceptable to the Company. Such physician's written determination of your Permanent Disability shall, upon delivery to the Company, be final and conclusive for purposes of this Agreement; provided, however, that no such determination shall be final and conclusive with respect to any disability coverage under paragraph 3(c).

(c) Your Involuntary Termination, as set forth in paragraph 6 below.

(d) Your Removal for Cause, as set forth in paragraph 7(a) below.

(e) Your voluntary termination (other than termination on account of death, Permanent Disability or termination by you for Good Reason) upon ninety (90) days prior written notice; provided, however, that the Company may waive such notice requirement in a written waiver delivered to you.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3601

Samsung Bioepis Exhibit 1017, pg. 3601

5. Death and Disability.

(a) If the Employment Term terminates by reason of your death or your Permanent Disability as provided in paragraph 4, then, except as provided in this paragraph 5(a), no further compensation will become payable to you under this Agreement, other than any earned but unpaid Base Salary, earned but unpaid bonuses, the pro rata portion of incentive compensation earned for services rendered through the date of your death or Permanent Disability, any deferred compensation and all other payments, benefits or fringe benefits to which you may be entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant (other than any severance plan) or this Agreement (collectively, "Entitlements"). Entitlements shall be calculated and paid as set forth in paragraph 5(c) below. You shall also be entitled to the Stock Option Treatment (as set forth in paragraph 8(f) below). In the event of your termination on account of your Permanent Disability, the Company shall pay you 100% of your Base Salary which you would have received during the eighteen (18) month period following your date of termination, such payment to be made in lump sum on the sixtieth (60th) day following termination, reduced by the projected amount of disability payments you are expected to receive during such period, calculated at the time of your termination, and assuming your continuous disability for the full (18) month period, and the Company shall also (i) continue to provide for insurance and other payments that are to be made under disability policies or plans paid for or maintained by the Company, (ii) continue to provide life insurance at a level of coverage comparable to the coverage in effect for you at the time of your termination on account of Permanent Disability, and (iii) pay you a monthly amount equal to COBRA premiums for medical and dental coverage as set forth in subparagraph (b) below, in each case upon the same terms and conditions (except for the requirement of your continued employment) for a period of eighteen (18) months following your date of termination.

(b) With respect to monthly amount for medical and dental coverage provided under paragraph 5(a), you shall be required to pay the applicable COBRA premium for you and your dependents, or to obtain coverage for you and your dependents under substitute arrangements, and you shall be paid a monthly amount by the Company equal to such amount, and to the extent you incur tax that you would not have incurred as an active employee as a result of the aforementioned coverage, you shall receive from the Company an additional gross-up payment in the amount necessary, subject to paragraph 14(o)(i), so that you will have no additional cost for receiving such items or any additional payment.

(c) Earned but unpaid bonus shall mean any declared but unpaid bonus for any prior bonus period and, if the bonus for the current bonus period is other than totally discretionary, a pro rata portion of the calculated bonus for the bonus period based on days in the bonus period prior to termination of your services compared to total days in the bonus period. Any incentive compensation shall be deemed earned and shall be paid based on actual results during the measuring period and a pro rata measurement of the days in the incentive period prior to termination of your services compared to total days in the incentive period. Such pro rata bonus and incentive compensation shall be paid to you at the same time and form that bonuses and incentive compensation are paid to other active participants. Any deferred compensation shall be paid in accordance with the terms of the applicable plan. Base Salary shall be paid in accordance with normal payroll practice.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3602

Samsung Bioepis Exhibit 1017, pg. 3602

6. Involuntary Termination.

(a) Involuntary Termination shall mean either your termination by the Company in accordance with paragraph 6(b) hereof, or your resignation in accordance with paragraph 6(c) hereof.

(b) Termination By The Company Without Cause: Your termination by the Company shall be considered to be "without cause" if (i) you are terminated or dismissed, for reasons other than your death, Permanent Disability or "Removal for Cause," as President or Chief Executive Officer, unless you have previously consented in writing to such removal or dismissal (which consent may be given or withheld in your sole discretion); provided, however, that your termination or dismissal as President shall not be a Termination by the Company without Cause if the person appointed President reports to you, or (ii) prior to your sixty-fifth (65th) birthday, the Company gives notice of nonextension of the Employment Term pursuant to paragraph 2 hereof.

(c) Termination By You For Good Reason: Your resignation shall be considered to be for Good Reason if you resign as President and Chief Executive Officer (whether or not you resign as a Director and, if Chairman of the Board, as Chairman of the Board) upon ninety (90) days' prior written notice within ninety (90) days after the occurrence of one of the following events: (i) your removal, dismissal or failure to be re-elected as President or Chief Executive Officer (other than on account of your termination for some other reason) or a de jure or de facto material reduction in your duties, title, responsibilities, authority, status, or reporting responsibilities (other than in connection with the appointment of a Chief Operating Officer or President who reports to you), unless you have previously consented in writing to such removal, dismissal or reduction (which consent may be given or withheld in your sole discretion); (ii) the failure to elect you, or your removal, dismissal or failure to be re-elected, as Chairman of the Board if the current Chairman of the Board ceases to serve as such; (iii) the failure of the Company to pay to you any amount due under this Agreement within ten (10) days after the later of its due date or your written demand for payment of such amount; (iv) any material breach by the Company of any provision of this Agreement which is not cured within thirty (30) days after your giving of written notice of such breach to the Company; (v) one year after a Change of Control, as defined in Exhibit A hereto, to the extent you are employed hereunder at that time; (vi) the relocation of the Company's principal executive office more than fifty (50) miles from the current location; or (vii) the failure of the Company to obtain and deliver to you a reasonably satisfactory written agreement from any successor to the Company as provided in paragraph 14(l).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3603

Samsung Bioepis Exhibit 1017, pg. 3603

(d) Upon an Involuntary Termination, you will become entitled to the benefits specified in paragraph 8 of this Agreement. In addition, you will be entitled to your Entitlements as calculated and paid in accordance with paragraph 5(c) above.

7. Removal for Cause.

(a) Removal for Cause shall mean the termination of your duties as President, Chief Executive Officer and, if you are then serving in such capacity, Chairman of the Board, effected by the Board of Directors of the Company (after a Board of Directors meeting for which you had at least ten (10) days prior written notice and at which you had the opportunity to have counsel present to represent you in connection with issues concerning your removal for cause) by reason of any one or more of the following, which individually or in the aggregate has a material adverse effect on the aggregate business or affairs of the Company and any Related Entity:

(i) your gross neglect of your duties, your willful and continuing refusal to perform your duties (other than, in any such case, because of a reasonably documented mental or physical illness), your refusal to obey any lawful order of the Board of Directors, or any material breach by you of any provision of paragraphs 11 or 12 of this Agreement, which, in any of the foregoing events, continues for more than thirty (30) days following your receipt of written notice from the Board of Directors that describes such breach or other event

(ii) your willful misconduct with respect to the business or affairs of the Company or of any Related Entity

(iii) your conviction of, or your plea of nolo contendere to, a misdemeanor involving embezzlement or fraud or other offense involving money or other property of the Company (other than a good faith dispute over expense account items), any criminal violation of the Securities Act of 1933 or the Securities Exchange Act of 1934, or any felony, provided your rights of appeal with respect to such matter have either lapsed or been exercised

(b) Upon your Removal for Cause, you will be entitled to your Entitlements as calculated and paid in accordance with paragraph 5(c) above. In such case, no amounts will be payable to you under paragraph 8 of this Agreement for any reason whatsoever.

(c) In the event of your voluntary termination in accordance with paragraph 4(e), you shall receive the same amounts as if you were Removed for Cause plus the Stock Option Treatment (as set forth in paragraph 8(f)).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3604

Samsung Bioepis Exhibit 1017, pg. 3604

8. Severance Benefits.

(a) Subject to paragraphs 8(b) and 8(e), upon an Involuntary Termination, you will become entitled to the following severance benefits:

(i) The Company will pay you an amount equal to one and one-quarter (1-1/4) times the sum of (x) your Base Salary in effect (or, if improperly reduced, required to be in effect) at the time of your Involuntary Termination and (y) the average of the annual bonuses paid or payable to you during the three (3) completed fiscal years prior to your Involuntary Termination; and such payment shall made to you in lump sum on the date specified in paragraph 8(g) below.

(ii) With respect to medical and dental coverage, you shall be required to pay the applicable COBRA premium for you and your dependents, or to obtain covering for you and your dependents under substitute arrangements, for eighteen (18) months, and you shall be reimbursed monthly by the Company for such amount, and to the extent you incur tax that you would not have incurred as an active employee as a result of the aforementioned coverage, you shall receive from the Company, subject to paragraph 14(o)(i), an additional gross-up payment in the amount necessary so that you will have no additional cost for receiving such items or any additional payment. The Company shall continue to provide you and your eligible dependents, upon the same terms and conditions (except for the requirement of your continued employment), with life insurance at a level of coverage comparable to the coverage in effect for you at the time of your Involuntary Termination for the eighteen (18) month period following your Involuntary Termination.

(b) Notwithstanding paragraph 8(a), upon your Involuntary Termination within three (3) years after a Change of Control, as defined in Exhibit A hereto, or within three (3) months prior thereto in anticipation of a Change of Control, you will become entitled to the following severance benefits in lieu of the amounts under paragraph 8(a) above:

(i) The Company will make a lump sum payment to you at on the date specified in paragraph 8(g) below of an amount equal to three (3) times the sum of (x) your Base Salary in effect (or, if improperly reduced, required to be in effect) at the time of your Involuntary Termination and (y) the average of the annual bonuses paid or payable to you during the three (3) completed fiscal years prior to your Involuntary Termination or, if higher, the three (3) completed fiscal years prior to the Change of Control.

(ii) Any bonus, vacation pay or other compensation accrued or earned under law or in accordance with the Company's policies applicable to you but not yet paid and any incurred but unreimbursed business expenses for the period prior to termination shall be payable, subject to paragraph 14(o)(i), in accordance with the Company's policies and the terms of the applicable plan

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3605

Samsung Bioepis Exhibit 1017, pg. 3605

(iii) With respect to medical and dental coverage, you shall be required to pay the applicable COBRA premium for you and your dependents, or to obtain covering for you and your dependents under substitute arrangements, for the thirty-six (36) month period following your Involuntary Termination, and you shall be reimbursed monthly by the Company for such amount, and to the extent you incur tax that you would not have incurred as an active employee as a result of the aforementioned coverage, you shall receive from the Company, subject to paragraph 14(o)(i), an additional gross-up payment in the amount necessary so that you will have no additional cost for receiving such items or any additional payment. The Company shall continue to provide you and your eligible dependents, upon the same terms and conditions (except for the requirement of your continued employment), with life insurance at a level of coverage comparable to the coverage in effect for you at the time of your Involuntary Termination for the thirty-six (36) month period following your Involuntary Termination.

(iv) All stock options, whether heretofore or hereafter, granted to you shall become fully vested and immediately exercisable and, if the basis were an action in anticipation of the Change of Control, the option shall remain exercisable (unless the original terms would otherwise end) at least through the Change of Control

(c) Each of your outstanding loans from the Company will become due and payable in accordance with their existing terms and provisions, and none of these loans will be forgiven or otherwise canceled in whole or in part.

(d) The Company agrees that if your employment with the Company is terminated during the Employment Term for any reason whatsoever, you are not required to seek other employment or to attempt in any way to reduce any amounts payable to you by the Company pursuant to this Agreement. Further, the amount of any payment or benefit provided for in this Agreement shall not be reduced by any compensation earned by you or benefit provided to you as the result of employment by another employer or otherwise. In addition, the amounts payable hereunder shall not be subject to setoff, counterclaim, recoupment, defense or other right which the Company may have against you or others, except upon obtaining by the Company of a final nonappealable judgment against you.

(e) In the event that you have received or commenced receipt of any payments or other rights under paragraphs 5(a) or 8(a), you shall not be entitled to any additional payments or rights under paragraphs 5(a), 8(a), or 8(b) with respect to any subsequent occurrence which might otherwise give rise to such payments or rights under such paragraphs, except as specifically provided with regard to paragraph 8(b).

(f) Notwithstanding anything to the contrary in this Agreement or any other agreement between you and the Company, the Company agrees that if your employment with the Company terminates during the Employment Term for any reason (other than a Removal for Cause), including a termination of employment pursuant to paragraphs 4(a), 4(b), 4(c) and 4(e), (i) all of your stock options and other equity awards shall continue to vest in accordance with the terms of the applicable grant agreement notwithstanding the employment termination, (ii) you (or your executors or administrators of your estate, in the case of your death) shall be entitled to exercise any of your stock options at any time during the original term of such options, and (iii) all agreements relating to your stock options or other equity shall be deemed amended to the extent inconsistent with the foregoing (such continued vesting and exercisability, the "Stock Option Treatment").

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3606

Samsung Bioepis Exhibit 1017, pg. 3606

(g) Any amounts payable and benefits or additional rights provided pursuant to paragraphs 8(a) or 8(b) beyond Entitlements ("Release Conditioned Amounts") shall be payable only if you deliver to the Company a release of all claims that you have or may have (and you do not revoke the release within the revocation period) within sixty (60) days after your termination in a form substantially in the form of Exhibit B hereto. Release Conditioned Amounts shall be paid to you in a lump sum, or shall commence if in installments, on the sixtieth (60th) day following your date of termination, with any missed installment payments paid in a lump sum on such date.

9. Excise Tax. In the event that you become entitled to payments and/or benefits which would constitute "parachute payments" within the meaning of Section 280G(b)(2) of the Internal Revenue Code of 1986, as amended, (the "Code"), the provisions of Exhibit C shall apply.

10. Proprietary Information and Inventions. You understand and acknowledge that:

(a) The Company is and will be engaged in a continuous program of research, design, development, production, and marketing with respect to its business.

(b) Your employment by the Company creates a relationship of confidence and trust between the Company and you with respect to certain information relating to the business and affairs of the Company or applicable to the business of any client, customer, consultant, partner, external collaborator, or service provider of the Company, which may be made known to you by the Company or by any client, customer, consultant, partner, external collaborator, or service provider of the Company, or learned by you during the period of your affiliation with the Company.

(c) The Company will possess information created, discovered, or developed by, or otherwise become known to, the Company (including, without limitation, information created, discovered, developed, or made known to you during the Employment Term) or in which property rights have been or may be assigned or otherwise conveyed to the Company (whether or not the information has commercial value in the business in which the Company is or proposes to be engaged) and is treated by the Company as confidential. All this information is "Proprietary Information," which includes, but is not limited to, systems, processes, formulae, data, functional specifications, computer software, programs and displays, know-how, improvements, discoveries, inventions, developments, designs, techniques, marketing plans, strategies, forecasts, new and proposed products, unpublished financial statements, budgets, projections, licenses, prices, costs, and customer, external collaborator, partner, client, and supplier lists, and any and all intellectual properties. The foregoing, however, shall not cover information generally known in the industry or which hereafter become generally known in the industry.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3607

Samsung Bioepis Exhibit 1017, pg. 3607

11. Ownership of Proprietary Information and Inventions.

(a) All Proprietary Information shall be the sole property of the Company and its assigns, and the Company and its assigns will be the sole owners of all inventions, patents, copyrights, trademarks, and other rights in connection therewith. You hereby assign to the Company any right you may have or acquire in such Proprietary Information. At all times, you will keep in strictest confidence and trust all Proprietary Information and you will not use or disclose any Proprietary Information without the written consent of the Company.

(b) If your employment with the Company is terminated for any reason, you will deliver to the Company all documents, notes, drawings, specifications, computer software, data, inventions, organisms, and other materials of any nature pertaining to any Proprietary Information, and will not take any of the foregoing, or any reproduction of any of the foregoing, that is embodied in any tangible medium of expression. This shall not limit you from retaining your personal phone directories and rolodexes.

(c) You will promptly disclose to the Company (or any persons designated by it) all discoveries, developments, designs, improvements, inventions, formulae, processes, techniques, computer software, strategies, know-how, and data, whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by you, either alone or jointly with others, during your employment by the Company, which result from carrying out your responsibilities to the Company, or result from the use of premises or property owned, leased, or contracted for by the Company (all such discoveries, developments, designs, improvements, inventions, formulae, processes, techniques, computer software, know-how, and data are referred to in this Agreement as Inventions). You will also promptly disclose to the Company, and the Company agrees to receive all such disclosures in confidence, all other discoveries, developments, designs, improvements, inventions, formulae, processes, techniques, computer software, strategies, know-how, and data, whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by you, either alone or jointly with others, during your employment by the Company for the purpose of determining whether they are Inventions, as that term is used in this Agreement. At all times during your employment by the Company you will use your reasonable business efforts to avoid conflicts of interest involving potential rights and claims of the Company and of third parties to Inventions, including those that might arise by virtue of your affiliation with a university or other medical institution concurrently with your employment by the Company and will take all action reasonably necessary and or desirable to minimize the probability of any such conflicts of interest and to maximize the likelihood that any Inventions made, conceived or developed or reduced to practice by you (alone or jointly with others) during your employment by the Company and which reasonably relate to the business of the Company will be and become the sole, unencumbered property of the Company, and no other third party (including, without limitation, any such university or other institution with whom you may also be affiliated) will have any rights thereto and that any such conflicts of interest be resolved in favor of the Company.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3608

Samsung Bioepis Exhibit 1017, pg. 3608

(d) All Inventions shall be the sole property of the Company and its assigns, and the Company and its assigns shall be the sole owner of all patents, copyrights, trademarks, and other rights in connection therewith. You hereby assign to the Company any rights you may have or acquire in such Inventions. You will assist the Company in every proper way as to all such Inventions (but at the Company's expense) to obtain and from time to time enforce patents, copyrights, trademarks, and other rights and protections on and enforcing such Inventions, as the Company may desire, together with any assignments thereof to the Company or persons designated by it. Your obligation to assist the Company in obtaining and enforcing patents, copyrights, trademarks, and other rights and protections relating to such Inventions in any and all countries shall continue beyond the Employment Term. If the Company is unable, after reasonable effort, to secure your signature on any document or documents needed to apply for or prosecute any patent, copyright, or other right or protection relating to an Invention, for any other reason whatsoever, you hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as your agent and attorney-in-fact, to act for and on your behalf to execute and file any such application or applications and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights, or similar protections thereon with the same legal force and effect as if executed by you and you hereby ratify, affirm, and approve all such lawfully permitted acts accordingly.

12. Restricted Covenant.

(a) You are aware that the services you perform for the Company are of a special, unique character. You also acknowledge your possession and future possession of Proprietary Information and the highly competitive nature of the business of the Company. Accordingly, you agree that, for the consideration set forth in this Agreement, you will not, without the written permission of the Company pursuant to Board of Directors authorization, during your employment under this Agreement and, if your employment ends as a result of your voluntary termination of employment pursuant to paragraph 4(e), for a period of one (1) year thereafter (six (6) months, in the event of any such termination after the occurrence of a Change of Control): (i) directly or indirectly engage or become interested or involved in any Competitive Business (as defined in subparagraph (b) below), whether such engagement, interest, or involvement shall be as an employer, officer, director, owner shareholder, employee, partner, consultant, or in any other capacity or relationship; provided, however, that this shall not preclude a passive investment of less than one (1%) of the stock of any publicly traded company; or (ii) materially assist others in engaging in any Competitive Business in the manner described in the foregoing clause (i); provided, further, that this shall not preclude you from providing investment banking services to or on behalf of an entity after your termination of employment that might otherwise be a Competitive Business so long as such services are to arrange a purchase, sale or other business combination for or with such entity or to arrange financing for such entity (including, without limitation, obtaining a bank loan for such entity or participating in the sale of the debt or equity securities of such entity).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3609

Samsung Bioepis Exhibit 1017, pg. 3609

You understand that this provision is not meant to prevent you from earning a living or fostering your career. It does intend, however, to prevent Competitive Businesses from gaining any unfair advantage from your knowledge of Proprietary Information. You understand that by making any other employer aware of this provision, that employer can take such action as to avoid your breach of this provision and to indemnify you in the event of a breach.

(b) The term "Competitive Business" means:

(i) For the period commencing on the date of this Agreement and ending on the date of your termination of employment any business or activity that is substantially the same as any business or activity of the Company as conducted by the Company or any Related Entity during such period; and

(ii) For the period thereafter, any business or activity described in subparagraph (i) above to the extent that on the date of your termination of employment such business or activity represents at least 10% of the research and development budget of the Company for the fiscal year in which your termination occurs; provided, however, that any business or activity of the Company shall be deemed to have been conducted by the Company at the time of your termination of employment if the Company has undertaken steps to commence such business or activity prior to your termination of employment. Notwithstanding the foregoing, the provisions of this paragraph shall not operate to preclude your employment with (or providing consulting services to) any company that has a market capitalization at the time of your termination of employment of at least $500 million.

13. Litigation Support. Subject to your other commitments, following the Employment Term, you shall make yourself reasonably available to cooperate (but only truthfully) with the Company and provide information as to matters with which you were personally involved, or have information on, while you were an officer of the Company and which are or become the subject of litigation or other dispute.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3610

Samsung Bioepis Exhibit 1017, pg. 3610

14. General Provisions.

(a) Death. Should you die before receipt of any or all severance payments to which you became entitled under paragraph 8, then the balance of the payments to which you are entitled shall continue to be paid in accordance with the terms hereof to the executors or administrators of your estate.

(b) General Creditor Status. The amounts to which you may become entitled hereunder shall be paid, when due, from the general assets of the Company, and no trust fund, escrow arrangements, or other segregated account shall be established as a funding vehicle for such payment. Accordingly, your right (or the right of the executors or administrators of your estate) to receive such benefits shall at all times be that of a general creditor of the Company and shall have no priority over the claims of other general creditors.

(c) Indemnification. During the Employment Term and thereafter, the Company shall indemnify you and hold you harmless to the fullest extent permitted by law against any judgments, fines, amounts paid in settlement and reasonable expenses (including reasonable attorneys' fees), and advance amounts necessary to pay the foregoing at the earliest time and to the fullest extent permitted by law, in connection with any claim, action or proceeding (whether civil or criminal) against you as a result of you serving as an officer or Director of the Company or in any capacity at the request of the Company in or with regard to any other entity, employee benefit plan or enterprise. This indemnification is in addition to and not in lieu of any other indemnification rights you may otherwise have.

(d) Remedies. Your obligations under paragraphs 11 or 12 of this Agreement will survive termination of your employment by the Company. You acknowledge that a remedy at law for any breach or threatened breach of such provisions would be inadequate and therefore agree that the Company may be entitled to injunctive relief and any other available rights and remedies in case of any such breach or threatened breach; provided, however, that nothing contained in this subparagraph (d) will be construed as prohibiting the Company from pursuing any other remedies available for any such breach or threatened breach.

(e) Interpretation. This Agreement shall be interpreted under the laws of the State of New York without regard to conflict of law provisions thereof.

(f) Notices. Any notice which a party is required or may desire to give under this Agreement will be given by personal delivery, air courier, or registered or certified mail, return receipt requested, addressed to you at the address of record with the Company and addressed to the Secretary of the Company at its principal office, or at such other place as either party may from time to time designate in writing given as aforesaid. The date of delivery of any notice or communication will be deemed to be (i) the date of delivery thereof, in the case of personal delivery; (ii) the day after the date when dispatched, in the case of air courier; and (iii) the date of receipt, in the case of mailing.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3611

Samsung Bioepis Exhibit 1017, pg. 3611

(g) Waivers. If either party shall waive any breach of any provision of this Agreement, he or it will not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

(h) Headings. The paragraph headings of this Agreement are for convenience only and will not be deemed to affect the meaning of the Agreement.

(i) Superseding. This Agreement supersedes all prior agreements between you and the Company relating to the subject of your personal services and severance benefits, including the letter agreement dated September 14, 1993, which is hereby terminated. The provisions of this Agreement may only be amended by written instrument signed by you and a member of the Board of Directors.

(j) No Guarantee of Employment or Service. Nothing in this Agreement is intended to provide you with any right to continue in the service of the Company for any period of specific duration, nor, except as specifically provided herein, to provide the Company with any right to require you to continue in the service of the Company.

(k) Amendment or Termination. This Agreement may not be amended or terminated orally, but only by a writing executed by the party to be charged.

(l) Assignment. None of the benefits to which you may become entitled hereunder may be assigned, transferred, pledged, or otherwise encumbered by you, and to the maximum extent permissible under law, such benefits will not be subject to the claims of your creditors or to levy, attachment, execution, or other legal process. This Agreement shall be binding upon and inure to the benefit of the Company, its successors and permitted assigns and your executors and heirs, provided that the Company may not assign the Agreement except in connection with a sale of all or substantially all of its assets and then only if said acquiror assumes in a writing delivered to you the obligations of the Company hereunder.

(m) Costs of Collection. In the event either party collects any part or all of the payments provided for hereunder or otherwise successfully enforces the terms of this Agreement by or through a lawyer or lawyers, the losing party shall pay all costs of such collection or enforcement, including reasonable legal fees and other fees and expenses which the successful party may incur plus interest ("Costs"); provided, however, that the Company shall not be entitled to recover any Costs from you unless an arbitrator determines that your action to recover any payment or to enforce the terms of this Agreement was not grounded on a reasonable good faith interpretation of the Agreement or that the action was undertaken for the primary purpose of harassing the Company. Interest shall be calculated at the prime rate as announced from time to time by Citibank, N.A. on all or any part of any amount to be paid to you hereunder that is not paid when due. The prime rate for each calendar quarter shall be the prime rate in effect on the first day of the calendar quarter. Any amounts due and payable to you on a favorable award of the arbitrator, pursuant to this paragraph 14(m) and paragraph 14(n), shall be paid within sixty (60) days following the date the arbitrator's decision becomes final.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3612

Samsung Bioepis Exhibit 1017, pg. 3612

(n) Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration, conducted before a panel of three (3) arbitrators in New York, New York, in accordance with the rules of the American Arbitration Association then in effect, and judgment may be entered on the arbitrators' award in any court having jurisdiction. The Company shall pay all costs of the American Arbitrator Association and the arbitrator. The decision upon arbitration shall be final and binding upon both you and the Company. Notwithstanding the foregoing, you shall be entitled to seek specific performance from a court of your right to be paid until the date of termination during the pendency of any dispute or controversy arising under or in connection with this Agreement and the Company shall have the right to obtain injunctive relief from a court pursuant to subparagraph (d) above.

(o) Section 409A. It is the intention of the parties hereto that the provisions of this Agreement comply with or be exempt from Section 409A of the Code and the regulations and guidance promulgated thereunder ("Section 409A") and that the Agreement shall be construed in accordance with such intention. Without limiting the generality of the foregoing, the Company and you agree as follows:

(i) Reimbursements payable to you as a result of the operation of paragraph 3(c), paragraph 3(d), paragraph 3(f) (other than the "Grandfathered Reimbursements"), paragraph 3(g), paragraph 3(h), paragraph 5, paragraph 8 (including paragraphs 8(b)(iii) and 8(f)), paragraph 14(c) or paragraph 14(m) hereof, or any other provision in this Agreement regarding reimbursement, shall be paid to you within sixty (60) days following the date upon which you become entitled to the reimbursement (or such earlier date specified in this Agreement), but in no event later than the end of the calendar year following the year in which the expenses to be reimbursed are incurred (or, in the case of payments under paragraph 14(m), the year following the year in which you become entitled to reimbursement). Tax gross-up payments (and related reimbursements) payable to you as a result of the operation of paragraph 3(f), paragraph 5(b), paragraph 8(f), paragraph 9 or Exhibit C hereof, or any other provision in this Agreement regarding tax gross-up payments, shall be paid to you within sixty (60) days following the date upon which the tax resulting in the gross-up is paid, but in no event later than the end of the calendar year following the year in which the tax resulting in the gross-up is paid. With regard to such reimbursements and payments under this paragraph or elsewhere in the Agreement, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, and (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, provided that the foregoing clause (ii) shall not be violated without regard to expenses reimbursed under any arrangement covered by Section 105(b) of the Code solely because such expenses are subject to a limit related to the period the arrangement is in effect.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3613

Samsung Bioepis Exhibit 1017, pg. 3613

(ii) Notwithstanding anything to the contrary herein, if you are a "specified employee" (within the meaning of Section 409A(a)(2)(B)(i) of the Code) with respect to the Company, (1) any amounts (or benefits) otherwise payable to or in respect of you under this Agreement pursuant to your termination of employment with the Company, which are deferred compensation under Section 409A, shall be delayed for a period of six months following such termination (or until death if earlier), so that taxes are not imposed on you pursuant to the operation of Section 409A, and shall be paid on first business day following the expiration such six month period and (2) any payments and benefits not required to be so delayed shall be paid or provided in accordance with this Agreement.

(iii) For purposes of amounts under this Agreement which are subject to Section 409A, your employment with the Company will not be treated as terminated unless and until such termination of employment constitutes a "separation from service" for purposes of Section 409A.

(iv) For purposes of Section 409A, to the extent that any payment payable under the Agreement is to be paid in installments, each such payment shall be treated as a separate identified payment for purposes of Section 409A. To the extent that the Agreement provides for a payment to be made on or before a specified date, the decision with respect to when to make such payment within the specified period shall be made in the sole discretion of the Company.

(v) The Company shall gross you up for any taxes, interest or penalties incurred by you under Section 409A as a result of any payments or benefits hereunder or otherwise due from the Company in such a manner that you will have no after tax cost as a result thereof, as soon as practicable but in no event later than the last day of the calendar year following the calendar year in which such tax, interest or penalty is paid. You agree to reasonably cooperate with the Company in order to avoid the imposition of such taxes, it being understood that such cooperation shall not require you to forgo receipt or receive a reduced amount of payments or benefits due hereunder.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3614

Samsung Bioepis Exhibit 1017, pg. 3614

Please indicate your acceptance by signing the enclosed copy of this letter and returning it to the Company.

Very truly yours,

REGENERON PHARMACEUTICALS, INC.

/s/ Arthur F. Ryan
Chairman of the Compensation
Committee of the Board of Directors

AGREED TO AND ACCEPTED BY:
LEONARD S. SCHLEIFER, M.D., Ph.D.

/s/ Leonard Schleifer

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3615

Samsung Bioepis Exhibit 1017, pg. 3615

EXHIBIT A

CHANGE OF CONTROL

For purposes of this Agreement, "Change of Control" shall be deemed to have occurred if the event set forth in any one of the following paragraphs shall have occurred:

(i) any "Person" (as defined in Section 3(a)(9) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as modified and used in Sections 13(d) and 14(d) thereof, except that such term shall not include (1) the Company, (2) a trustee or other fiduciary holding securities under an employee benefit plan of the Company, (3) an underwriter temporarily holding securities pursuant to an offering of such securities, or (4) a corporation owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their ownership of stock of the Company) is or becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person any securities acquired directly from the Company) representing 20% or more of the Company's then outstanding securities, excluding any Person who is an officer or director of the Company or who becomes such a Beneficial Owner in connection with a transaction described in clause (A) of paragraph (iii) below; or

(ii) the following individuals cease for any reason to constitute a majority of the number of directors then serving: individuals who, on the date hereof, constitute the Board of Directors and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including but not limited to a consent solicitation, relating to the election of directors of the Company) whose appointment or election by the Board of Directors or nomination for election by the Company's shareholders was approved or recommended by a vote of at least two-thirds (2/3) of the directors then still in office who either were directors on the date hereof or whose appointment, election or nomination for election was previously so approved or recommended; or

(iii) there is consummated a merger or consolidation of the Company with any other corporation other than (A) a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) at least 60% of the combined voting power of the voting securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person any securities acquired directly from the Company) representing 20% or more of the combined voting power of the Company's then outstanding securities; or

(iv) the shareholders of the Company approve a plan of complete liquidation or dissolution of the Company or there is consummated an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, other than a sale or disposition by the Company of all or substantially all of the Company's assets to an entity at least 75% of the combined voting power of the voting securities of which are owned by Persons in substantially the same proportions as their ownership of the Company immediately prior to such sale.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3616

Samsung Bioepis Exhibit 1017, pg. 3616

EXHIBIT B

FORM OF RELEASE

To: Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591-6707
Attention: [General Counsel]

1. **Termination.** (a) I hereby acknowledge that my employment with Regeneron Pharmaceuticals, Inc. (the "Company") [will terminate] [has terminated] on, (the "Termination Date") pursuant to provisions of paragraphs 8 of my employment agreement dated as of December 20, 2002 with the Company (the "Employment Agreement"), that the Company will not have an obligation to rehire me or to consider me for reemployment after the Termination Date and that my employment with the Company is permanently and irrevocably severed.

(b) I hereby confirm my resignation from my position as President and Chief Executive Officer of the Company and that I will not be eligible for any benefits or compensation after the Termination Date, other than as specifically provided hereunder and in paragraphs 3 and 8 of the Employment Agreement [or in any capacity as a director of the Company]. In addition, effective as of the Termination Date, I hereby resign from all offices, directorships, trusteeships, committee memberships and fiduciary capacities held with, or on behalf of, the Company or any of its affiliates or any benefit plans of the Company or any of its affiliates [other than as a director]. These resignations will become irrevocable on the Effective Date of this Agreement, as defined in Section 6 below.

2. **Consideration.** I acknowledge that this General Release is being executed in accordance with paragraph 8(g) of the Employment Agreement.

3. **General Release.** (a) For and in consideration of the payments to be made and the promises set forth under the Employment Agreement, I, for myself and for my heirs, dependents, executors, administrators, trustees, legal representatives and assigns (collectively referred to as "Releasors"), hereby forever release, waive and discharge the Company, its affiliates, employee benefit and/or pension plans or funds, insurers, successors and assigns, and all of its or their past, present and/or future directors, officers, trustees, agents, members, partners, counsel, employees, fiduciaries, administrators, representatives, successors and assigns, whether acting on behalf of the Company or its affiliates or in their individual capacities (collectively referred to as "Releasees"), from any and all claims, demands, causes of action, fees and liabilities of any kind whatsoever, whether known or unknown, which Releasors ever had, now have, or hereafter may claim to have against Releasees by reason of any actual or alleged act, omission, transaction, practice, policy, procedure, conduct, occurrence, or other matter up to and including the date of my execution of this General Release, in connection with, or in any way related to or arising out of, my employment, service as a director, service as a trustee, service as a fiduciary or termination of any of the foregoing with the Company.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3617

Samsung Bioepis Exhibit 1017, pg. 3617

(b) Without limiting the generality of the foregoing, this General Release is intended and shall release the Releasees from any and all claims, whether known or unknown, which Releasors ever had, now have, or may hereafter claim to have against the Releasees including, but not limited to, (i) any claim of discrimination or retaliation under the Age Discrimination in Employment Act ("ADEA"), Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act ("ADA"), the Employee Retirement Income Security Act of 1974 or the Family and Medical Leave Act; (ii) any claim under the New York State Human Rights Law and the New York City Administrative Code; (iii) any other claim (whether based on federal, state or local law, statutory or decisional) relating to or arising out of my employment, the terms and conditions of such employment, the termination of such employment and/or any of the events relating directly or indirectly to or surrounding the termination of such employment, including, but not limited, breach of contract (express or implied), wrongful discharge, tortious interference, detrimental reliance, defamation, emotional distress or compensatory or punitive damages; and (iv) any claim for attorney's fees, costs, disbursements and the like.

(c) I further acknowledge and agree that by virtue of the foregoing, I have waived all relief available to me (including without limitation, monetary damages, equitable relief and reinstatement) under any of the claims and/or causes of action waived in Sections 3(a) and (b) above. Therefore I agree that I will not seek or accept any award or settlement from any source or proceeding (including, but not limited to, any proceeding brought by any other person or by any government agency) with respect to any claim or right waived in this General Release. I further agree, to the maximum extent permitted by law, that I will not sue or commence any proceeding (judicial or administrative), or participate in any action, suit or proceeding (unless compelled by legal process or court order), against the Company (or any of its affiliates), with respect to any claim released by Sections 3(a) and (b) above, other than a claim contesting the validity of the release under applicable provisions of the ADEA. I also warrant and represent that as of the date I sign this Agreement, I have not taken or engaged in any of the acts described in the foregoing sentences. I understand that this release has neither the purpose nor intent of interfering with my protected right to file a charge with or participate in an investigation or proceeding pursuant to the statutes administered and enforced by the EEOC, specifically: the ADEA, the Equal Pay Act, Title VII of the Civil Rights Act of 1964 and the ADA. I understand that I will not breach this release if I file a charge with or participate in an investigation or proceeding pursuant to the statutes administered and enforced by the EEOC. However, by signing this release, I understand that I waive any right I may have to recover money or other relief in any lawsuit or proceeding brought by me or by an agency or third party, including the EEOC, on my behalf. If, notwithstanding the foregoing promises and understandings, I violate this Section 3(c), I shall be required, to the maximum extent permitted by law, to indemnify and hold harmless the Company (and its affiliates) from and against any and all demands, assessments, judgments, costs, damages, losses and liabilities, and attorneys' fees and other expenses which result from, or are incident to, such violation.

(d) Notwithstanding anything herein to the contrary, the sole matters to which the release and covenants in this Section 3 do not apply are: (i) my rights of indemnification and directors and officers liability insurance coverage which I was entitled immediately prior to the Termination Date under the Company's By-laws or otherwise with regard to my service as an officer and director of the Company (including, without limitation, under paragraph 14(c) of the Employment Agreement); (ii) my rights under any tax-qualified pension or tax deferred annuity plan or claims for accrued vested benefits under any other employee benefit plan, program, policy or arrangement maintained by the Company or under COBRA; (iii) my rights under the provisions of the Employment Agreement which are intended to survive termination of employment (including claims to payments, benefits or entitlements specifically payable or provided under the Employment Agreement); or (iv) my rights as a stockholder or as a director of the Company.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3618

Samsung Bioepis Exhibit 1017, pg. 3618

4. **Governing Law; Enforceability**. The interpretation of this General Release will be construed and enforced in accordance with the laws of the State of New York without regard to that state's principles of conflicts of law. If, at any time after the execution of this General Release, any provision of this General Release will be held to be illegal or unenforceable by a court of competent jurisdiction, solely such provision will be of no force or effect.

5. **Acknowledgement**. I acknowledge that I have been advised by the Company in writing to consult, and I have consulted, independent legal counsel of my choice before signing this General Release. I further acknowledge that I have had the opportunity to consult independent legal counsel and to consider the terms of this General Release for a period of at least 21 days. I further acknowledge that I have carefully read this General Release in its entirety; that I have had an adequate opportunity to consider it and to consult with any advisors of my choice about it; that I have consulted with independent legal counsel of my choice who has answered to my satisfaction all questions I had regarding this General Release; that I understand all the terms of this General Release and their significance; that I am legally competent to execute this Agreement; that I have not relied on any statements or explanations made by the Company, any agent of the Company or its counsel; that I knowingly and voluntarily assent to all the terms and conditions contained herein; and that I am signing this General Release voluntarily and of my own free will.

6. **Effective Date**. I further acknowledge that this General Release will not become effective until the eighth day following my execution of this General Release (the "Effective Date"), and that I may at any time prior to the Effective Date revoke this General Release by delivering written notice of revocation to the Company, at 777 Old Saw Mill River Road, Tarrytown, New York 10591-6707, to the attention of the [General Counsel]. In the event that I revoke this General Release prior to the eighth day after its execution, this General Release will automatically be null and void.

7. **Survival**. The provisions in the Employment Agreement which are intended to survive termination of employment hall survive and continue in full force and effect.

Acknowledged and Agreed:
REGENERON PHARMACEUTICALS, INC.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3619

Samsung Bioepis Exhibit 1017, pg. 3619

EXHIBIT C

GOLDEN PARACHUTE PROVISION

(a) (i) In the event that you shall become entitled to payments and/or benefits provided by this Agreement or any other amounts in the "nature of compensation" (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement with the Company, any person whose actions result in a change of ownership or effective control covered by Section 280G(b)(2) of the Code or any person affiliated with the Company or such person) as a result of such change in ownership or effective control (collectively the "Company Payments"), and such Company Payments will be subject to the tax (the "Excise Tax") imposed by Section 4999 of the Code (and any similar tax that may hereafter be imposed by any taxing authority) the Company shall pay to you at the time specified in subsection (d) below (x) an additional amount (the "Gross-up Payment") such that the net amount retained by you, after deduction of any Excise Tax on the Company Payments and any U.S. federal, state, and for local income or payroll tax upon the Gross-up Payment provided for by this paragraph (a), but before deduction for any U.S. federal, state, and local income or payroll tax on the Company Payments, shall be equal to the Company Payments and (y) an amount equal to the product of any deductions disallowed for federal, state or local income tax purposes because of the inclusion of the Gross-Up Payment in your adjusted gross income multiplied by your actual applicable marginal rate of federal, state or local income taxation, respectively, for the calendar year in which the Gross-Up Payment is to be made.

(ii) Notwithstanding the foregoing, if it shall be determined that you are entitled to a Gross-Up Payment, but that if the Company Payments (other than that portion valued under Q&A 24(c) of the proposed regulations under Section 280G of the Code(the "Stock Vesting Value")) (the "Cash Payments") are reduced by the amount necessary such that the receipt of the Company Payments would not give rise to any Excise Tax (the "Reduced Payment") and the Reduced Payment (other than the Stock Vesting Value) would not be less than 90% of the Cash Payment, then no Gross-Up Payment shall be made to you and the Cash Payments, in the aggregate, shall be reduced to the Reduced Payments (other than the Stock Vesting Value). If the Reduced Payments is to be effective, payments shall be reduced as mutually agreed between the Company and you or, in the event the parties cannot agree, in the following order (1) any lump sum severance based on a multiple of Base Salary or annual bonus, (2) any other cash amounts payable to you and (3) any benefits valued as parachute payments.

(iii) In the event that the Internal Revenue Service or court ultimately makes a determination that the excess parachute payments plus the base amount is an amount other than as determined initially, an appropriate adjustment shall be made with regard to the Gross-Up Payment or Reduced Payment, as applicable to reflect the final determination and the resulting impact on whether (ii) applies.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3620

Samsung Bioepis Exhibit 1017, pg. 3620

(b) For purposes of determining whether any of the Company Payments and Gross-up Payments (collectively the "Total Payments") will be subject to the Excise Tax and the amount of such Excise Tax, (x) the Total Payments shall be treated as "parachute payments" within the meaning of Section 280G(b)(2) of the Code, and all "parachute payments" in excess of the "base amount" (as defined under Section 280G(b)(3) of the Code) shall be treated as subject to the Excise Tax, unless and except to the extent that, in the opinion, delivered to the Company and you at a level of more likely than not, of the Company's independent certified public accountants appointed prior to any change in ownership (as defined under Section 280G(b)(2) of the Code) or tax counsel selected by such accountants (the "Accountants") such Total Payments (in whole or in part) either do not constitute "parachute payments," represent reasonable compensation for services actually rendered within the meaning of Section 280G(b)(4) of the Code in excess of the "base amount" or are otherwise not subject to the Excise Tax, and (y) the value of any non-cash benefits or any deferred payment or benefit shall be determined by the Accountants in accordance with the principles of Section 280G of the Code. In the event that the Accountants are serving (or decline to serve) as accountant or auditor for the individual, entity or group effecting the Change of Control, you may appoint another nationally recognized accounting firm or law firm to make the determinations hereunder (which accounting firm or law firm shall then be referred to as the "Accountants" hereunder). All determinations hereunder shall be made by the Accountants which shall provide detailed supporting calculations both to the Company and you at such time as it is requested by the Company or you. If the Accountants determine that payments under this Agreement must be reduced pursuant to this paragraph, they shall furnish you with a written opinion to such effect. The determination of the Accountants shall be final and binding upon the Company and you, subject to the other provisions herein.

(c) For purposes of determining the amount of the Gross-up Payment, you shall be deemed to pay U.S. federal income taxes at actual rate of U.S. federal income taxation in the calendar year in which the Gross-up Payment is to be made and state and local income taxes at the rate of taxation in the state and locality of your residence for the calendar year in which the Company Payment is to be made, net of the reduction in U.S. federal income taxes which could be obtained from deduction of such state and local taxes if paid in such year. In the event that the Excise Tax is subsequently determined by the Accountants to be less than the amount taken into account hereunder at the time the Gross-up Payment is made, you shall repay to the Company, at the time that the amount of such reduction in Excise Tax is finally determined, the portion of the prior Gross-up Payment attributable to such reduction (plus the portion of the Gross-up Payment attributable to the Excise Tax and U.S. federal, state and local income tax imposed on the portion of the Gross-up Payment being repaid by you if such repayment results in a reduction in Excise Tax or a U.S. federal, state and local income tax deduction), plus interest on the amount of such repayment at the rate provided in Section 1274(b)(2)(B) of the Code. Notwithstanding the foregoing, in the event any portion of the Gross-up Payment to be refunded to the Company has been paid to any U.S. federal, state and local tax authority, repayment thereof (and related amounts) shall not be required until actual refund or credit of such portion has been made to you, and interest payable to the Company shall not exceed the interest received or credited to you by such tax authority for the period it held such portion. Furthermore, to the extent the foregoing provision shall be deemed to create a loan of a personal nature in violation of Section 402 of the Sarbanes-Oxley Act of 2002, the provision for repayment shall be null and void. You and the Company shall mutually agree upon the course of action to be pursued (and the method of allocating the expense thereof) if your claim for refund or credit is denied.

In the event that the Excise Tax is later determined by the Accountant or the Internal Revenue Service to exceed the amount taken into account hereunder at the time the Gross-up Payment is made (including by reason of any payment the existence or amount of which cannot be determined at the time of the Gross-up Payment), the Company shall make an additional Gross-up Payment in respect of such excess (plus any interest or penalties payable with respect to such excess) at the time that the amount of such excess is finally determined.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3621

Samsung Bioepis Exhibit 1017, pg. 3621

(d) The Gross-up Payment or portion thereof provided for in subsection (c) above shall be paid not later than the thirtieth (30th) day following an event occurring which subjects you to the Excise Tax; provided, however, that if the amount of such Gross-up Payment or portion thereof cannot be finally determined on or before such day, the Company shall pay to you on such day an estimate, as determined in good faith by the Accountant, of the minimum amount of such payments and shall pay the remainder of such payments (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code), subject to further payments pursuant to subsection (c) hereof, as soon as the amount thereof can reasonably be determined, but in no event later than the ninetieth day after the occurrence of the event subjecting you to the Excise Tax. In the event that the amount of the estimated payments exceeds the amount subsequently determined to have been due, such excess shall constitute a loan by the Company to you, payable on the fifth day after demand by the Company (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code), provided that, to the extent the foregoing provision shall be deemed to create a loan of a personal nature in violation of Section 402 of the Sarbanes-Oxley Act of 2002, the provision for repayment shall be null and void.

(e) In the event of any controversy with the Internal Revenue Service (or other taxing authority) with regard to the Excise Tax, you shall permit the Company to control issues related to the Excise Tax (at its expense), provided that such issues do not potentially materially adversely affect you, but you shall control any other issues. In the event the issues are interrelated, you and the Company shall in good faith cooperate so as not to jeopardize resolution of either issue, but if the parties cannot agree you shall make the final determination with regard to the issues. In the event of any conference with any taxing authority as to the Excise Tax or associated income taxes, you shall permit the representative of the Company to accompany you, and you and your representative shall cooperate with the Company and its representative.

(f) The Company shall be responsible for all charges of the Accountant.

(g) The Company and you shall promptly deliver to each other copies of any written communications, and summaries of any verbal communications, with any taxing authority regarding the Excise Tax covered by this Exhibit C.

(h) Any Gross-Up Payments hereunder shall be paid in the time and manner set forth in Section 14(o)(i) and (ii) of the Agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3622

Samsung Bioepis Exhibit 1017, pg. 3622

REGENERON PHARMACEUTICALS, INC.

CHANGE IN CONTROL SEVERANCE PLAN

As amended and restated, effective November 14, 2008

INTRODUCTION

The purposes of this Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan (this "Plan") are (i) to help the Company (as defined below) retain key employees of the Company, (ii) to help maintain the focus of such employees on the business of the Company and to mitigate the distractions caused by the possibility that the Company may be the target of an acquisition; and (iii) to provide certain benefits to such employees in the event their employment is terminated (or constructively terminated) after, or in contemplation of, a change in control. The possibility of such terminations and the uncertainty it creates may result in the loss or distraction of key employees of the Company to the detriment of the Company and its shareholders.

The Company's Board of Directors (the "Board") considers the retention of key employees and the avoidance of such loss and distraction to be essential to protecting and enhancing the best interests of the Company and it shareholders. The Board also believes that when a change in control is perceived as imminent, or is occurring, the Board should be able to receive and rely on disinterested service from employees regarding the best interests of the Company and its shareholders without concern that employees might be distracted or concerned by the personal uncertainties and risks created by a change in control.

Accordingly, in order to accomplish the above purposes, the Board has caused the Company to adopt this Plan, as amended and restated effective November 14, 2008 (the "Effective Date").

1. Definitions. For the purpose of this Plan the foregoing terms shall have the following meanings:

(a) "Anticipatory Termination" means a termination of an Eligible Executive's employment by the Company without Cause or by an Eligible Executive for Good Reason that occurs after a tender offer is announced for the Company or after material discussions have occurred with a possible acquirer with regard to a Transaction (as defined in the definition of "Change in Control" below), provided, that such offer or discussions have not terminated.

(b) "Average Bonus" shall mean the average amount in each of the Company's last three (3) completed fiscal years prior to the termination of employment (or if higher the last three (3) completed fiscal years prior to the Change in Control) awarded to an Eligible Executive as an annual bonus for such years (or if not employed on the last day of three prior completed fiscal years, the average over those fiscal years when employed on the last day of a fiscal year or, if no such dates, the average of the Average Bonus of all Eligible Executives in the Eligible Executive's Group; provided, that any bonus awarded to an Eligible Executive for a fiscal year during which he or she was employed for only a portion of the year shall be annualized to reflect a full year's bonus for such year).

(c) "Bonus" shall mean the product of (i) the Eligible Executive's annual base salary rate for the year in which the Date of Termination occurs (which is calculated immediately prior to any reduction in base salary (if any) if such termination is by the Eligible Executive for Good Reason) multiplied by (ii) the average of the percentages that bonuses represented of base salary for the fiscal years utilized to determine Average Bonus.

(d) "Cause" shall mean, as to each Eligible Executive, (i) the Eligible Executive's willful misconduct involving the Company or its assets, business or employees or in the performance of his or her duties which is materially injurious to the Company (in a manner which would affect the Company economically or as to its reputation); (ii) the Eligible Executive's indictment for, or conviction of, or pleading guilty or nolo contendre to, a felony (provided that for this purpose, a felony shall cover any action or inaction that is a felony or crime under federal, state or local law in the United States (collectively, "U.S. law") and any action or inaction which takes place outside of the United States, if it would be a felony under U.S. law); (iii) the Eligible Executive's continued and substantial failure to attempt in good faith to perform his or her duties with the Company (other than failure resulting from the Eligible Executive's incapacity due to physical or mental illness or injury), which failure has continued for a period of at least ten (10) days after written notice thereof from the Company; (iv) the Eligible Executive's breach of any material provisions of any written agreement with the Company, which breach, if curable, is not cured within ten (10) days after written notice thereof from the Company; or (v) the Eligible Executive's failure to attempt in good faith to promptly follow a written direction of the Board or a more senior officer, provided that the failure shall not be considered "Cause" if the Eligible Executive, in good faith, believes that such direction, or implementation thereof, is illegal or inconsistent with the Company's Code of Conduct and he or she promptly so notifies the Chairman of the Board in writing. No act or failure to act by an Eligible Executive shall be deemed to be "willful" if the Eligible Executive believed in good faith that such action or non-action was in, or not opposed to, the best interests of the Company.

(e) A "Change in Control" shall mean the occurrence of any of the following events: (i) any "Person" (as defined in Section 3(a)(9) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as modified and used in Sections 13(d) and 14(d) thereof, except that such term shall not include (1) the Company, (2) a trustee or other fiduciary holding securities under an employee benefit plan of the Company, (3) an underwriter temporarily holding securities pursuant to an offering of such securities, or (4) a corporation owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their ownership of stock of the Company) is or becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing thirty-five percent (35%) or more of the Company's then outstanding securities, excluding any Person who is an officer or director of the Company or who becomes such a Beneficial Owner in connection with a transaction described in clause (A) of subsection (iii) below; (ii) the following individuals cease for any reason to constitute a majority of the number of directors then serving: individuals who, on the Effective Date, constitute the Board and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including but not limited to a consent solicitation, relating to the election of directors of the Company) whose appointment or election by the Board or nomination for election by the Company's shareholders was approved or recommended by a vote of at least two-thirds (2/3) of the directors then still in office who either were directors on the Effective Date or whose appointment, election or nomination for election was previously so approved or recommended; (iii) there is consummated a merger or consolidation of the Company with any other corporation other than (A) a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) at least sixty percent (60%) of the combined voting power of the voting securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company representing thirty-five percent (35%) or more of the combined voting power of the Company's then outstanding securities; or (iv) the shareholders of the Company approve a plan of complete liquidation or dissolution of the Company or there is consummated an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, other than a sale or disposition by the Company of all or substantially all of the Company's assets to an entity at least seventy-five percent (75%) of the combined voting power of the voting securities of which are owned by Persons in substantially the same proportions as their ownership of the Company immediately prior to such sale; subsections (iii) and (iv) above each a "Transaction". For the avoidance of doubt, the term "securities" shall refer solely to the Company's Common Stock, par value $.001 per share and Class A Stock, par value $.001 per share.

(f) "Code" shall mean the Internal Revenue Code of 1986, as amended.

(g) "Committee" shall mean the Compensation Committee of the Board.

(h) "Company" shall mean Regeneron Pharmaceuticals, Inc. and any successor thereto; provided, that for the purposes of this Plan, other than any obligation to make payments or provide benefits hereunder and as to the definition of Change in Control, "Company" shall also include all of the Company's subsidiaries (as defined in Code Section 424(f)).

(i) "Disability" shall mean, as to each Eligible Executive, the Eligible Executive's failure to have performed his or her material duties and responsibilities as a result of physical or mental illness or injury for more than one hundred eighty (180) days during a three hundred sixty-five (365) day period.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3624

Samsung Bioepis Exhibit 1017, pg. 3624

(j) "Eligible Executives" shall mean Group 1 Executives and Group 2 Executives.

(k) "Equity Grant" shall mean any stock option, restricted stock award, or other equity grant under the Company's long-term incentive plans.

(l) "Good Reason" shall mean, as to each Eligible Executive, a termination (including, if applicable, by retirement in accordance with Company policy) by the Eligible Executive and effected by a written notice given within ninety (90) days after the occurrence of the Good Reason event. For purposes of this Agreement, "Good Reason" shall mean, as to each Eligible Executive, the occurrence of any of the following events without the Eligible Executive's express written consent which event is not cured within thirty (30) days after written notice thereof from the Eligible Executive to the Company: (i) any material diminution in the Eligible Executive's position, duties, responsibilities, title or authority, or the assignment to the Eligible Executive of duties and responsibilities materially inconsistent with his or her position, except in connection with the Eligible Executive's termination for Cause or as a result of death, or temporarily as a result of the Eligible Executive's incapacity or other absence for an extended period; (ii) any material breach by the Company of any material provision of any written agreement with the Eligible Executive or failure to timely pay any compensation obligation to the Eligible Executive; (iii) a reduction in the Eligible Executive's annual base salary or target bonus opportunity (if any); (iv) a relocation of the Eligible Executive's principal business location to an area outside of a fifty (50) mile radius of the Eligible Executive's current principal business location or (v) a failure by the Company to comply with this Plan.

(m) "Group 1 Executive" shall mean an officer or other executive who has been designated by the Committee as a Group 1 Executive in accordance with Section 2 below.

(n) "Group 2 Executive" shall mean an officer or other executive who has been designated by the Committee as a Group 2 Executive in accordance with Section 2 below.

(o) "Severance Multiplier" shall mean one for Group 1 Executives and two for Group 2 Executives.

(p) A termination "without Cause" shall mean a termination of an Eligible Executive's employment by the Company other than for a termination for Cause or due to Disability.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3625

Samsung Bioepis Exhibit 1017, pg. 3625

2. Eligible Executives. Eligible Executives shall consist of those officers and other executives of the Company as the Committee in its sole discretion designates in writing to participate in the Plan. At the time the Committee designates an employee as an Eligible Executive, the Committee shall also designate whether such Eligible Executive is a Group 1 Executive or a Group 2 Executive. The Committee may, in its sole discretion, terminate an employee's participation in the Plan as an Eligible Executive by providing not less than one (1) year's prior written notice to the employee (a "Plan Participation Termination Notice") at any time following the two (2) year anniversary of the Effective Date; provided, that no Plan Participation Termination Notice shall be effective after a Change in Control (whether sent before or after). The Committee may designate additional Eligible Executives or change the designation of any Group 1 Executive to a Group 2 Executive at any time in its sole discretion.

3. Termination of Employment in Connection with a Change in Control. Subject to the provisions of Section 24 hereof:

(a) If (i) a Change in Control occurs and an Eligible Executive's employment with the Company is terminated by the Company without Cause or by the Eligible Executive for Good Reason at any time within two (2) years after the Change in Control or (ii) there was an Anticipatory Termination and the Change in Control has taken place within one hundred eighty (180) days thereafter, such Eligible Executive shall be entitled to the amounts provided in Section 4 upon such termination or, if an Anticipatory Termination, upon the Change in Control (less any severance benefits previously paid or provided by the Company).

(b) In the event of an Anticipatory Termination, if any Equity Grants in the name of the applicable Eligible Executive would vest as a result of the Anticipatory Termination had it occurred after the Change in Control (or the Equity Grant otherwise would have vested pursuant to its terms on or prior to the Change in Control if not for the Anticipatory Termination), any such Equity Grant that otherwise would be forfeited shall not be forfeited pending a determination of whether or not a Change in Control occurs within one hundred eighty (180) days thereafter (the "Determination Period"), but during the Determination Period no unvested Equity Grant shall vest or be exercisable and no dividends shall be payable unless and until the Change in Control takes place during the Determination Period. If a Change in Control occurs during the Determination Period, then the Equity Grants that would have vested during the Determination Period absent the Anticipatory Termination and any Equity Grants that would vest on the Change in Control or, upon a without Cause or Good Reason termination within two (2) years thereafter, shall become vested upon the Change in Control and the exercise period of all Equity Grants that are subject to exercise conditions shall be extended, to the extent applicable, to the later of (i) the permitted exercise dates after the Anticipatory Termination provided in the plan or grant assuming the Change in Control had happened immediately prior to the Anticipatory Termination and (ii) the date which is thirty (30) days following the first date after such Change in Control in which shares of the Company could be traded by the Eligible Executive on the applicable market under the Company's or its subsidiary's trading window policies but, (x) not beyond the last day of extension permitted under Code Section 409A without such Equity Grant being deemed subject to the additional tax under Code Section 409A, and (y) in no event beyond the initial expiration date of the grant. In the event an Equity Grant would expire after an Anticipatory Termination and prior to it becoming exercisable (including as a result of a Change in Control) as a result of either (x) or (y) of the forgoing sentence, it may be exercised during the thirty (30) day period prior to its expiration (or, if in connection with a Change in Control, such other period (whether shorter or longer) that applies to other similar Equity Grants) but the transaction shall be held in escrow pending a determination of whether a Change in Control has taken place during the one hundred eighty (180) day period after termination of the Eligible Executive's employment.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3626

Samsung Bioepis Exhibit 1017, pg. 3626

4. Compensation on Change in Control Termination. (a) If, pursuant to Section 3, an Eligible Executive is entitled to amounts and benefits under this Section 4, such Eligible Executive shall receive the following payments and benefits from the Company:

(i) (A) any base salary, bonus, paid time off or other compensation accrued or earned under law or in accordance with the Company's policies and practices applicable to the Eligible Executive but not yet paid; (B) subject to submission of appropriate documentation, any incurred but unreimbursed business expenses for the period prior to the Eligible Executive's termination payable in accordance with the Company's policies and practices; and (C) any other amounts or vested benefits due under the then applicable employee benefit (including without limitation any Supplemental Executive Retirement Plan), equity or incentive plans of the Company then in effect, applicable to the Eligible Executive (including, without limitation, the Company's 401(k) Savings Plan) as shall be determined and paid in accordance with such plans;

(ii) subject to Section 4(b) and Section 8 hereof, within ten (10) days after the satisfaction of the requirements of Section 8 hereof (or, if such termination occurred prior to a Change in Control, within ten (10) days after the latter of the aforesaid date or the Change in Control), a lump sum payment equal to the product of (A) the Severance Multiplier times (B) the sum of (x) the Eligible Executive's annual base salary rate (which is calculated immediately prior to any reduction in base salary (if any) if such termination is by the Eligible Executive for Good Reason) and (y) the Eligible Executive's Average Bonus;

(iii) subject to Section 4(b) and Section 8 hereof, within ten (10) days after the satisfaction of the requirements of Section 8 hereof (or, if such termination occurred prior to a Change in Control, within ten (10) days after the latter of the aforesaid date or the Change in Control), a pro rata Bonus payment for the year in which the Eligible Executive is terminated based on the portion of the year the Eligible Executive was employed;

(iv) to the extent not paid pursuant to Section 4(a)(i)(A) above, any earned but unpaid bonus for a previously completed fiscal year of the Company; provided that such bonus shall be paid to the Eligible Executive in the year following the completed fiscal year of the Company when other executives of the Company receive their bonuses (but not later than 2 ½ months following the completion of such fiscal year);

(v) subject to Section 4(b) and Section 8 hereof, continued coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), or otherwise, under the Company health plans in which the Eligible Executive and his/her dependents participated immediately prior to the Eligible Executive's Date of Termination, or materially equivalent plans thereto (the "Health Plans"), for the Eligible Executive and the Eligible Executive's dependents until the earlier of (A) (x) one (1) year following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 1 Executive, or (y) eighteen (18) months following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 2 Executive, and (B) the Eligible Executive's becoming eligible to participate in the health plan of another employer; provided, that the Eligible Executive timely elects such coverage and pays the same premium amount for such coverage as the Eligible Executive would pay if an active employee immediately prior to the Change in Control (the "Existing Premium Amount"); and further provided that such coverage shall cease to the extent that the providing of such coverage would violate applicable law. Furthermore, to the extent that the applicable coverage period in this Section 4(a)(v) can not be provided under the Company's policies or, if the providing of such coverage would result in taxation of the benefits under Code Section 105(h) (or a successor provision), the Company shall make payments to the Eligible Executive of the premiums it had been paying for such coverage for the Eligible Executive (but on a fully taxed grossed-up basis). In addition, if a Group 2 Executive has not become eligible to participate in the health plan of another employer by the date immediately following the expiration of the eighteen (18) month period referred to in the preceding sentence, the Company shall make a monthly payment to the Eligible Executive of the monthly premium it had been paying for such coverage for the Eligible Executive (but on a fully taxed grossed-up basis) for up to a maximum of six (6) months following the expiration of such eighteen (18) month period (or, if earlier, until the Eligible Executive becomes eligible to participate in the health plan of another employer).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3627

Samsung Bioepis Exhibit 1017, pg. 3627

(vi) subject to Section 4(b) and Section 8 hereof, continued coverage (at Company expense to the same extent as payments were made by the Company while the Eligible Executive was an active employee) in all welfare benefit plans (other then those covered by (v) above) and financial/tax advisory and preparatory services that the Eligible Executive participated in prior to his/her Date of Termination for (x) one (1) year following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 1 Executive, or (y) two (2) years following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 2 Executive. All such coverage shall be provided in a manner such that it either (i) does not provide for a "deferral of compensation" within the meaning of Code Section 409A or (ii) complies with the requirements of Code Section 409A. Payment to an Eligible Executive of a lump sum amount equal to the premium payable for such coverage shall only be permitted if such payment may be made without violating the requirements of Code Section 409A.

(b) Severance payments and benefits pursuant to Section 4(a)(ii), (iii) or (iv) hereof are intended to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4). Nevertheless, if the Company determines in good faith that any payment provided under such sections or otherwise under Section 4(a) would cause a violation of Code Section 409A if paid within the first six (6) months after termination of an Eligible Executive's employment, such amount(s) shall not be paid to such Eligible Executive during such six (6) month period but shall instead be paid or provided to such Eligible Executive immediately after the end of such six (6) month period, in a lump sum (without interest). Thereafter, payments to such Eligible Executive shall be made in accordance with the Company's normal payroll practices. In the event that continuation of any benefit would in the good faith judgment of the Company cause a violation of Code Section 409A if provided at Company cost during the first six (6) months after the Date of Termination of an Eligible Executive, if the Eligible Executive wants such benefit continuation, he/she shall pay to the Company the full cost therefor during such six (6) month period and the Company shall reimburse him/her for such cost in a lump sum payment immediately after the end of such six (6) month period.

5. Excise Tax. In the event that an Eligible Executive shall become entitled to payments and/or benefits provided by this Plan or any other amounts in the "nature of compensation" (whether pursuant to the terms of this Plan or any other plan, arrangement or agreement with the Company, including, without limitation, an award agreement under an equity compensation plan, any Person whose actions result in a change of ownership or effective control covered by Section 280G(b)(2) of the Code or any person affiliated with the Company or such person) as a result of a Change in Control (collectively the "Company Payments"), and if such Company Payments will be subject to the tax (the "Excise Tax") imposed by Section 4999 of the Code (and any similar tax that may hereafter be imposed by any taxing authority) the amounts of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Eligible Executive to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Eligible Executive (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Eligible Executive minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. The Eligible Executive may elect which payments and benefits shall be reduced to accomplish the foregoing, but, if the Eligible Executive does not make such an election, the first benefit to be reduced is acceleration of vesting of any stock option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur, and the second benefit to be reduced shall be any cash payments under this Plan.

(a) For purposes of determining whether any of the Company Payments will be subject to the Excise Tax and the amount of such Excise Tax, (x) the Company Payments shall be treated as "parachute payments" within the meaning of Section 280G(b)(2) of the Code, and all "parachute payments" in excess of the "base amount" (as defined under Code Section 280G(b)(3) of the Code) shall be treated as subject to the Excise Tax, unless and except to the extent that, in the opinion of the Company's independent certified public accountants appointed prior to any change in ownership (as defined under Code Section 280G(b)(2)) or tax counsel selected by such accountants (the "Accountants") such Company Payments (in whole or in part) either do not constitute "parachute payments," including giving effect to the recalculation of stock options in accordance with Treasury Regulation Section 1.280G-1 Q/A33, represent reasonable compensation for services actually rendered within the meaning of Section 280G(b)(4) of the Code in excess of the "base amount" or are otherwise not subject to the Excise Tax, and (y) the value of any non-cash benefits or any deferred payment or benefit shall be determined by the Accountants in accordance with the principles of Section 280G of the Code. To the extent permitted under Revenue Procedure 2003-68, the value determination shall be recalculated to the extent it would be beneficial to the Eligible Executive, at the request of the Eligible Executive.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3628

Samsung Bioepis Exhibit 1017, pg. 3628

(b) For purposes of making the calculation hereunder, the Eligible Executive shall be deemed to pay U.S. federal income taxes at the highest marginal rate of U.S. federal income taxation in effect in the calendar year in which the Company Payments are to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of the Eligible Executive's residence in effect for the calendar year in which the Company Payments are to be made, net of the maximum reduction in U.S. federal income taxes which could be obtained from deduction of such state and local taxes if paid in such year.

(c) In the event of any controversy with the Internal Revenue Service (or other taxing authority) with regard to the Excise Tax, the Eligible Executive shall permit the Company to control issues related to the Excise Tax (at its expense), provided that such issues do not potentially materially adversely affect the Eligible Executive, but the Eligible Executive shall control any other issues. In the event the issues are interrelated, the Eligible Executive and the Company shall in good faith cooperate so as not to jeopardize resolution of either issue, but if the parties cannot agree the Eligible Executive shall make the final determination with regard to the issues. In the event of any conference with any taxing authority as to the Excise Tax or associated income taxes, the Eligible Executive shall permit the representative of the Company to accompany the Eligible Executive, and the Eligible Executive and the Eligible Executive's representative shall cooperate with the Company and its representative.

(d) The Company shall be responsible for all charges of the Accountants.

(e) The Company and the Eligible Executive shall promptly deliver to each other copies of any written communications, and summaries of any verbal communications, with any taxing authority regarding the Excise Tax.

6. Notice of Termination. After a Change in Control, any purported termination of an Eligible Executive's employment (other than by reason of death) shall be communicated by written Notice of Termination from the Company to the Eligible Executive or from the Eligible Executive to the Company, as the case may be, in accordance with Section 19. For purposes of this Plan, a "Notice of Termination" shall mean a notice which shall set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of an Eligible Executive's employment. Further, a Notice of Termination for Cause after a Change in Control is required to include a copy of a resolution duly adopted by the affirmative vote of not less than two-thirds (2/3) of the entire membership of the Board (at a meeting of the Board which was called and held for the purpose of considering such termination and at which the Eligible Executive had the right to attend and speak) finding that, in the good faith opinion of the Board, the Eligible Executive has engaged in conduct set forth in the definition of Cause herein, and specifying the particulars thereof in detail.

7. Date of Termination. "Date of Termination," with respect to any purported termination of an Eligible Executive's employment after a Change in Control, shall mean the date specified in the Notice of Termination (or, in the case of a termination by the Company, if no date is specified, the date which is ten (10) days from the date of such Notice of Termination) and, in the case of a termination by an Eligible Executive for Good Reason, shall be thirty (30) days from the date such Notice of Termination is given.

8. Acceptance and Release. Any and all amounts payable and benefits or additional rights provided pursuant to Sections 4 (a)(ii), (iii), (v) and (vi) above shall only be payable if the Eligible Executive executes and delivers to the Company within forty five (45) days following the Date of Termination an Acceptance Form and Release in the form attached hereto as Appendix B discharging all claims of the Eligible Executive which may have occurred up to the Date of Termination applicable to the Eligible Executive (with such changes therein as may be necessary to make it valid and encompassing under applicable law). Notwithstanding anything herein to the contrary, if an Eligible Executive materially breaches any of the provisions of Section 10 of this Plan, the Company may cease all payments and benefits due to such Eligible Executive thereafter under Sections 4(a) (ii), (iii), (v) and (vi) above (other than as required by law).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3629

Samsung Bioepis Exhibit 1017, pg. 3629

9. No Duty to Mitigate/Set-off. The Company agrees that the Eligible Executive shall not be required to seek other employment or to attempt in any way to reduce any amounts payable to the Eligible Executive by the Company pursuant to this Plan. Further, other than as set forth in Section 4(a)(v)(B), the amount of any payment or benefit provided for in this Plan shall not be reduced by any compensation earned by an Eligible Executive or benefit provided to an Eligible Executive as the result of employment by another employer, unemployment insurance payments or otherwise. Except as otherwise provided herein and apart from any disagreement between an Eligible Executive and the Company concerning interpretation of this Plan or any term or provision hereof, the Company's obligations to make the payments provided for in this Plan and otherwise to perform its obligations hereunder shall not be affected by any circumstances, including without limitation, any set-off, counterclaim, recoupment, defense or other right which the Company may have against an Eligible Executive. The amounts due under Section 4 are inclusive, and in lieu of, any amounts payable under any other salary continuation or cash severance arrangement of the Company and to the extent paid or provided under any other such arrangement shall be offset against the amount due hereunder.

10. Confidentiality, Non-Solicitation and Cooperation.

(a) In consideration of participating in this Plan, by the execution and delivery to the Committee of an Acknowledgement and Agreement to Restrictive Covenants set forth on Appendix A attached hereto, if the Eligible Executive is employed by the Company at the time of a Change in Control or has been terminated in an Anticipatory Termination within one hundred eighty (180) days prior thereto, each Eligible Executive agrees to the following agreements:

(i) during the Eligible Executive's employment with the Company and thereafter, the Eligible Executive agrees not to, directly or indirectly, for any reason whatsoever, communicate or disclose to any unauthorized person, firm or corporation, or use for the Eligible Executive's own account, without the prior written consent of the Board or the Chief Executive Officer of the Company (the "CEO"), any proprietary processes, trade secrets or other confidential data or information of the Company and its related and affiliated companies concerning their businesses or affairs, accounts, products, services or customers, it being understood, however, that the obligations of this Section 10(a) shall not apply to the extent that the aforesaid matters (i) are disclosed in circumstances in which the Eligible Executive is legally required to do so, provided that the Eligible Executive gives the Company prompt written notice of receipt of notice of any legal proceedings so as the Company has the opportunity to obtain a protective order, or (ii) become known to and available for use by the public other than by the Eligible Executive's wrongful act or omission;

(ii) during the Eligible Executive's employment with the Company and thereafter, the Eligible Executive agrees to fully cooperate with the Company or its counsel in connection with any matter, investigation, proceeding or litigation regarding any matter in which the Eligible Executive was involved during the Eligible Executive's employment with the Company or to which the Eligible Executive has knowledge based on the Eligible Executive's employment with the Company; and

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3630

Samsung Bioepis Exhibit 1017, pg. 3630

(iii) during the Eligible Executive's employment with the Company and for the one (1) year period thereafter, if the Eligible Executive is receiving the amounts and benefits provided under Section 4, the Eligible Executive agrees that he or she will not individually or on behalf of any other person, firm, corporation or other entity (actions of such other person, firm, corporation or other entity not being attributable to the Eligible Executive unless he or she is personally involved therewith), solicit, induce, hire or retain any employee of the Company (or any person who had been such an employee in the prior three (3) months) to leave the employ of the Company and to accept employment or retention as an independent contractor with, or render services to or with any other person, firm, corporation or other entity unaffiliated with the Company or take any action to assist or aid any other person, firm, corporation or other entity in identifying, soliciting, hiring or retaining any such employee; provided, the Eligible Executive may serve as a reference after the Eligible Executive is no longer employed by the Company, but not with regard to any entity with which the Eligible Executive is affiliated or from which the Eligible Executive is receiving compensation and this provision shall not be violated by general advertising not specifically targeted at employees of the Company.

(b) Because the Company's remedies at law for a breach or threatened breach of any of the provisions of this Section 10 would be inadequate, in the event of such a breach or threatened breach by an Eligible Executive, in addition to any remedies at law, the Company shall be entitled to seek equitable relief in the form of specific performance, a temporary restraining order, a temporary or permanent injunction or any other equitable remedy which may then be available.

(c) If it is determined by a court of competent jurisdiction that any restriction in this Section 10 is excessive in duration or scope or is unreasonable or unenforceable, such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted.

(d) The agreements set forth in this Section 10 are in addition to any other activity limitations an Eligible Executive is subject to under any other agreement between the Eligible Executive and the Company or any other plan or arrangement of the Company applicable to the Eligible Executive.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3631

Samsung Bioepis Exhibit 1017, pg. 3631

11. Service with Subsidiaries. For purposes of this Plan, employment by a subsidiary or a parent of the Company shall be deemed to be employment by the Company and references to the Company shall include all such entities, except that the payment obligation hereunder shall be solely that of the Company. A Change in Control, however, as used in this Plan, shall refer only to a Change in Control of the Company.

12. Liability Insurance; Indemnification.

If an Eligible Executive is receiving the payments and benefits under Section 4, then:

(a) the Company shall continue to cover such Eligible Executive, or cause the Eligible Executive to be covered, under any director and officer insurance maintained after the Change in Control for directors and officers of the Company (whether by the Company or another entity) at the highest level so maintained for any other past or active director or officer with regard to any action or omission of the Eligible Executive while an officer or director of the Company. Such coverage shall continue for any period during which the Eligible Executive may have any liability for the aforesaid actions or omissions; and

(b) following a Change in Control, the Company shall, with regard to matters related to such Eligible Executive's period of employment with the Company, indemnify the Eligible Executive to the fullest extent permitted or authorized by the Company's bylaws against any claims, suits, judgments, expenses (including reasonable attorney fees), with advancement of legal fees and disbursements to the fullest extent permitted by law, arising from, out of, or in connection with the Eligible Executive's services as an officer or director of the Company, as an officer or director of any affiliate for which the Eligible Executive was required to serve as such by the Company or as a fiduciary of any benefit plan of the Company or any affiliate.

13. Funding. This Plan shall be funded out of the general assets of the Company as and when benefits are payable under this Plan. To the extent that any Eligible Executive acquires a right to receive payments under this Plan, such right shall not be secured by any assets of the Company or any of its affiliated companies. The Eligible Executives shall be general creditors of the Company. Any assignment, lien or other encumbrance by an Eligible Executive of the amounts and benefits provided under this Plan shall be null and void. If the Company decides in its sole discretion to establish any advance accrued reserve on its books against the future expense of benefits payable hereunder, or if the Company decides in its sole discretion to fund a trust under this Plan, such reserve or trust shall not under any circumstances be deemed to be an asset of this Plan.

14. Administration of this Plan.

(a) The general administration of this Plan on behalf of the Company (as "Plan Administrator" under Section 3(16)(A) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA")) shall be placed with the Committee.

(b) The Company may, in its sole discretion, pay or reimburse the members of the Committee for all reasonable expenses incurred in connection with their duties hereunder.

(c) Decisions of the Committee shall be made by a majority of its members attending a meeting at which a quorum is present (which meeting may be held telephonically), or by written action in accordance with applicable law. Subject to the terms of this Plan and provided that the Committee acts in good faith, the Committee shall have complete authority to determine an Eligible Executive's participation and benefits under this Plan, to interpret and construe, in its sole discretion, the provisions of this Plan, and to make decisions in all disputes involving the rights of any person interested in this Plan. All decisions by the Committee shall be made in the Committee's sole discretion and shall be final and binding on all persons having or claiming any interest in this Plan. Notwithstanding the foregoing, all decisions of the Committee after a Change in Control shall be reviewable on a *de novo* basis by an arbitrator or court , as applicable.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3632

Samsung Bioepis Exhibit 1017, pg. 3632

(d) The Committee may delegate any and all of its powers and responsibilities hereunder to other persons by formal resolution filed with and accepted by the Board. Any such delegation shall not be effective until it is accepted by the Board and the persons designated and may be rescinded at any time by written notice from the Committee to the person to whom the delegation is made.

(e) The Committee may employ such legal counsel, accountants and other persons as may be required in carrying out its work in connection with this Plan.

(f) The Committee shall maintain such accounts and records regarding the fiscal and other transactions of this Plan and such other data as may be required to carry out its functions under this Plan and to comply with all applicable laws.

(g) The Company shall be the Plan Administrator for the purposes of any applicable law and shall be responsible for the preparation and filing of any required returns, reports, statements or other filings with appropriate governmental agencies. The Company shall also be responsible for the preparation and delivery of information to persons entitled to such information under any applicable law.

(h) The Company shall indemnify, to the full extent permitted by law and its Certificate of Incorporation and By-laws (but only to the extent not directly covered by insurance) its officers and directors, (and any employee involved in carrying out the functions of the Company under this Plan), each member of the Committee, and any person designated pursuant to Section 14 (d) above, against any expenses, including amounts paid in settlement of a liability, which are reasonably incurred in connection with any legal action to which such person is a party by reason of his or her duties or responsibilities with respect to this Plan, except with regard to matters as to which he or she shall be adjudged in such action to be liable for gross negligence, willful misconduct or fraud in the performance of his or her duties.

15. ERISA Provisions (Including Claims Procedures). This Plan is intended to be a "top hat" welfare benefit plan within the meaning of U.S. Department of Labor Regulation Section 2520.104-24. Administrative provisions about this Plan are contained in Appendix C hereto. This Plan document, including the Appendices hereto, shall constitute the Plan document and shall be distributed to Eligible Executives in this form.

16. Employee Benefit Plans. The amounts and benefits specified in Section 4 hereof shall not be paid to any Eligible Executive as an employee and no Eligible Executive shall be eligible to participate in employee benefit plans maintained by the Company following the Date of Termination applicable to such Eligible Executive except as specifically provided herein or in such benefit plan(s). Amounts paid pursuant to Section 4 shall not be taken into account for purposes of determining contributions to or calculating accrued benefits under the employee benefit plans maintained by the Company, except for accrued amounts that would be so taken into account pursuant to the terms of the applicable plan.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3633

Samsung Bioepis Exhibit 1017, pg. 3633

17. Successors; Binding Agreement. In addition to any obligations imposed by law upon any successor to the Company, the Company will require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company to expressly assume and agree in writing to be obligated to make the payments and provide the benefits under this Plan in the same manner and to the same extent that the Company would have been obligated under this Plan if no such succession had taken place. This Plan shall inure to the benefit of and be enforceable by each Eligible Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If an Eligible Executive shall die while any amount would still be payable to such Eligible Executive hereunder, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Plan to the executors, personal representatives or administrators of such Eligible Executive's estate as if the Eligible Executive had continued to live. No rights or obligations hereunder may be assigned by an Eligible Executive.

18. Amendment and Termination. This Plan shall continue until terminated by the Company in accordance with this Section 18, but the Plan shall cover only the first Change in Control occurring hereafter. The Company reserves the right to amend or terminate, in whole or in part, any or all of the provisions of this Plan by action of the Board or the Committee at any time and for any reason prior to a Change in Control, provided that in no event shall any amendment which reduces an Eligible Executive's right to payment and/or benefits under this Plan or any termination of this Plan be effective as to any Eligible Executive then participating in this Plan prior to the one (1) year anniversary such amendment or Plan termination is adopted by the Board or the Committee, and provided further that no such amendment or termination that is not effective prior to a Change in Control shall be effective after a Change in Control.

19. Notices. Any notice or other communication required or permitted under this Plan shall be in writing and shall be delivered personally, or sent by registered mail, postage prepaid. Any such notice shall be deemed given when so delivered personally, or, if mailed, five (5) days after the date of deposit in the United States mails,

(i) If to the Company, to:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: Chief Executive Officer

(ii) If to an Eligible Executive, to his or her last shown address on the books of the Company.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3634

Samsung Bioepis Exhibit 1017, pg. 3634

20. Separability. If any provisions of this Plan (including the appendices hereto) shall be declared to be invalid or unenforceable, in whole or in part, (by a court of competent jurisdiction) such invalidity or unenforceability shall not affect the validity of the remaining provisions of this Plan (including the appendices hereto).

21. Legal Fees.

(a) In the event the Company does not make the payments due hereunder on a timely basis (as determined by an arbitrator) and the matter is arbitrated pursuant to Section 22 below, if the Eligible Executive prevails in such arbitration, the Company shall pay all costs of such arbitration, including reasonable legal fees and other reasonable fees and expenses which the Eligible Executive may incur (on a tax grossed up basis, to the extent such amounts are taxable to the Eligible Executive).

(b) The Company shall pay to the Eligible Executive interest at the prime lending rate (as reported from time to time by The Wall Street Journal) on all or any part of any amount to be paid to Eligible Executive hereunder that is not paid when due. The prime rate for each calendar quarter shall be the prime rate in effect on the first day of the calendar quarter.

22. Arbitration. Any dispute or controversy arising under or in connection with this Plan shall be settled exclusively by arbitration conducted in the City of New York in the State of New York under the Commercial Arbitration Rules then prevailing of the American Arbitration Association and such submission shall request the American Arbitration Association to: (i) appoint an arbitrator experienced and knowledgeable concerning the matter then in dispute; (ii) require the testimony to be transcribed; (iii) require the award to be accompanied by findings of fact and the statement for reasons for the decision; and (iv) request the matter to be handled by and in accordance with the expedited procedures provided for in the Commercial Arbitration Rules. The determination of the arbitrators, which shall be based upon a de novo interpretation of this Plan, shall be final and binding and judgment may be entered on the arbitrators' award in any court having jurisdiction. The Company shall pay all costs of the American Arbitration Association and the arbitrator.

23. Withholding. The Company shall have the right to make such provisions as it deems necessary or appropriate to satisfy any obligations it reasonably believes it may have to withhold federal, state or local income or other taxes incurred by reason of payments pursuant to this Plan. In lieu thereof, the Company shall have the right to withhold the amounts of such taxes from any other sums due or to become due from the Company to an Eligible Executive upon such terms and conditions as the Committee may prescribe.

24. Code Section 409A. This Plan is intended to comply with the applicable requirements of Code Section 409A and shall be limited, construed, interpreted and administered in accordance with such intent. The Company reserves the right to amend the provisions of this Plan at any time in order to avoid the imposition of the additional tax under Code Section 409A on any payments to be made hereunder. The Company shall indemnify the Eligible Executives for any taxes, interest or penalties incurred under Code Section 409A as a result of any payments or benefits hereunder in such a manner that the Eligible Executive will have no after tax cost as a result thereof. Without limiting the generality of the foregoing:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3635

Samsung Bioepis Exhibit 1017, pg. 3635

(a) For purposes of this Plan, the employment of Eligible Executives with the Company will not be treated as terminated unless and until such termination of employment constitutes a "separation from service" for purposes of Section 409A of the Code.

(b) The Acceptance Form and Release described in Section 8 hereof shall be provided to the Eligible Executive and shall be required to be executed by the Eligible Executive in a time period which will not result in severance payments made to the Eligible Executive hereunder failing to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4). Severance payments pursuant to Section 4(a) hereof are intended to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4).

(c) If the provisions of Section 3(b) are applicable to an equity or equity-based award subject to the provisions of Section 409A of the Code, payment of such awards shall be made, if provided for in Section 3(b), in a time period which will not result in such payments failing to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4).

(d) To the extent necessary to comply with the provisions of Section 409A of the Code and the guidance issued thereunder (A) reimbursements or tax gross-up payments to an Eligible Executive pursuant to Section 4, Section 12, Section 21, this Section 24 or otherwise hereunder shall be made not later than the end of the calendar year following the year in which the reimbursable expense is incurred or tax subject to a gross-up provision is paid by the Eligible Executive, as applicable, and shall otherwise be made in a manner that complies with the requirements of Treasury Regulation Section 1.409A-3(i)(l)(iv).

25. Non-Exclusivity of Rights. Nothing in this Plan shall prevent or limit an Eligible Executive's continuing or future participation in any benefit, bonus, incentive, equity or other plan or program provided by the Company for which the Eligible Executive may qualify, nor shall anything herein (except Section 8) limit or otherwise prejudice such rights as the Eligible Executive may have under any other currently existing plan, agreement as to employment, or termination from employment with the Company or any other contractual or statutory entitlements. Amounts that are vested benefits or those which an Eligible Executive is otherwise entitled to receive under any other plan or program of the Company, at or subsequent to the Termination Date applicable to such Eligible Executive, shall be payable in accordance with such other plan or program, except as otherwise specifically provided herein. With the exception of the provisions in this Agreement regarding vesting and exercisability of Equity Grants following an Anticipatory Termination, nothing in this Plan will affect any term or provision of any stock option award between an Eligible Executive and the Company and the rights set forth in this Plan are in addition to, and not in lieu of, the terms of any such award agreements. Notwithstanding the foregoing, an Eligible Executive shall not be entitled to received duplicative severance payments and benefits and, to the extent that an Eligible Executive is entitled to severance payments and benefits under any other plan or agreement, such Eligible Executive shall be entitled to the greater of the payments and benefits thereunder or hereunder but not under both plans or agreements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3636

Samsung Bioepis Exhibit 1017, pg. 3636

26. At Will Employment. This Plan does not constitute a contract of employment and, subject to any other agreement between an Eligible Executive and the Company, the Company reserves the right to terminate an Eligible Executive's employment at any time with or without reason or notice (unless otherwise prohibited by law), subject to the payment and other provisions hereof.

27. Governing Law. The construction, interpretation and administration of this Plan shall be governed by ERISA. To the extent not so governed, it shall be construed, interpreted, and governed in accordance with the laws of the State of New York without reference to rules relating to conflicts of law.

IN WITNESS WHEREOF, this amended and restated Plan has been adopted effective as of November 14, 2008, and Regeneron Pharmaceuticals, Inc. has caused this instrument to be signed by its officer or representative duly authorized on this 14th day of November 2008.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski

Name: Stuart Kolinski

Title: Senior Vice President & General Counsel

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3637

Samsung Bioepis Exhibit 1017, pg. 3637

Appendix A

FORM OF

ACKNOWLEDGEMENT AND AGREEMENT TO RESTRICTIVE COVENANTS

The Compensation Committee
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591

Reference is hereby made to the Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, as amended and restated effective November 14, 2008 (the "Plan"). Any capitalized term used but not defined herein shall have the meaning ascribed to such term in the Plan.

In consideration of participation in the Plan as an Eligible Executive, the undersigned hereby acknowledges and agrees that if the undersigned is employed by the Company at the time of a Change in Control or has been terminated in an Anticipatory Termination within one hundred eighty (180) days prior thereto, the undersigned shall be bound by the restrictive covenants and agreements set forth in Section 10 of the Plan.

_____

[Name of Eligible Executive]

Effective Date:

Appendix B

ACCEPTANCE FORM AND RELEASE

Release

1. I agree and acknowledge that the payments and other benefits provided pursuant to the Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan ("Plan"), as amended and restated effective November 14, 2008 and my rights under any equity grant (i) are in full discharge of any and all liabilities and obligations of the Company to me, monetarily or with respect to employee benefits or otherwise, including but not limited to any and all obligations arising under any alleged written or oral employment agreement, policy, plan or procedure of the Company and/or any alleged understanding or arrangement between me and the Company; and (ii) exceed any payment, benefit, or other thing of value to which I might otherwise be entitled under any policy, plan or procedure of the Company and/or any agreement between me and the Company.

2. In consideration for the payments and benefits to be provided to me pursuant to the Plan, I forever release and discharge the Company from any and all claims. This includes claims that are not specified in this Acceptance Form and Release (this "Release"), claims of which I am not currently aware, claims under: (i) the Age Discrimination in Employment Act, as amended; (ii) Title VII of the Civil Rights Act of 1964, as amended; (iii) the Americans with Disabilities Act, as amended; (iv) the Employee Retirement Income Security Act of 1974, as amended (excluding claims for accrued, vested benefits under any employee benefit pension plan of the Company in accordance with the terms and conditions of such plan and applicable law); (v) the Workers' Adjustment and Retraining Notification Act; (vi) the Family and Medical Leave Act; (vii) any claim under the New York State Human Rights Law and the New York City Administrative Code; (viii) any other claim (whether based on federal, state, or local law, statutory or decisional) relating to or arising out of my employment, the terms and conditions of such employment, the separation of such employment, and/or any of the events relating directly or indirectly to or surrounding the separation of that employment, including, but not limited to, breach of contract (express or implied), wrongful discharge, detrimental reliance, defamation, emotional distress or compensatory or punitive damages; and (ix) any claim for attorneys' fees, costs, disbursements and/or the like. Notwithstanding anything herein to the contrary, the sole matters to which this Release does not apply are (i) the rights of indemnification and directors and officers liability insurance coverage to which I was entitled immediately prior to my termination; (ii) my rights under any tax-qualified pension plan or claims for accrued vested benefits under any other employee benefit plan, policy or arrangement maintained by the Company or under the Consolidated Omnibus Budget Reconciliation Act of 1985; and (iii) my rights under the specific terms of any equity grant.

3. This Release applies to me and to anyone who succeeds to my rights, such as my heirs, executors, administrators of my estate, trustees, and assigns. This Release is for the benefit of (i) the Company, (ii) any related corporation or entity, (iii) any director, officer, employee, or agent of the Company or of any such related corporation or entity, or (iv) any person, corporation or entity who or that succeeds to the rights of the Company or of any such person, corporation or entity.

4. I acknowledge that I: (a) have carefully read in their entirety the Plan, this Release [and the information attached as Appendix I provided pursuant to the Older Workers Benefit Protection Act]; (b) have had an opportunity to consider fully for at least [twenty-one (21)] [forty-five (45)] days the terms of the Plan, this Release [and information attached as Appendix I]; (c) have been advised by the Company in writing to consult with an attorney of my choosing in connection with the Plan, this Release [and the information attached as Appendix I]; (d) fully understand the significance of all of the terms and conditions of the Plan, Release [and the information attached as Appendix I], and have discussed them with my independent legal counsel, or have had a reasonable opportunity to do so; (e) have had answered to my satisfaction any questions I have asked with regard to the meaning and significance of any of the provisions of the Plan, this Release [and the information attached as Appendix I]; and (f) am signing this Release voluntarily and of my own free will and assent to all the terms and conditions contained herein and contained in the Plan and the Release.

5. I understand that I will have [twenty-one (21)] [forty-five (45)] days from the date of receipt of this Release [and information attached as Appendix I] to consider the terms and conditions of those documents. I may execute and thereby accept this Release by signing and sending it to _____. After executing this Release and returning it to _____, I shall have seven (7) days (the "Revocation Period") to revoke this Release by indicating my desire to do so in writing delivered by no later than 5:00 p.m. on the seventh (7th) day following the date I sign and return this Release. The effective date of this Release shall be the eighth (8th) day following my signing and return of this Release. If the last day of the Revocation Period falls on a Saturday, Sunday or holiday, the last day of the Revocation Period will be deemed to be the next business day. In the event I do not accept this Release, or in the event I revoke this Release during the Revocation Period, my rights under the Plan, this Release, including but not limited to my rights to receive payments and other benefits from the Company, shall be deemed automatically null and void.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3640

Samsung Bioepis Exhibit 1017, pg. 3640

Print Name: _____ Date: _____

Employee

Signature: _____

Employee

STATE OF NEW YORK)

) ss:

COUNTY OF _____)

On this ___ day of _____ _____, before me personally came _____ to be known and known to me to be the person described and who executed the foregoing Release, and (s)he duly acknowledged to me that (s)he executed the same.

_____

Notary Public

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3641

Samsung Bioepis Exhibit 1017, pg. 3641

ACCEPTANCE FORM AND RELEASE

Acceptance Form:

I have read the Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, as amended and restated effective November 14, 2008 ("Plan") and the accompanying Release [and the information attached as Appendix I] and hereby accept the benefits provided under the Plan, subject to the terms and conditions set forth in the Plan and the Release.

Print Name: _____ Date: _____
Employee

Signature: _____
Employee

STATE OF NEW YORK)
) ss:
COUNTY OF _____)

On this ___ day of _____ _____, before me personally came _____ to be known and known to me to be the person described and who executed the foregoing Release, and (s)he duly acknowledged to me that (s)he executed the same.

_____

Notary Public

APPENDIX C

PROVISIONS RELATING TO ERISA

A. Claims Procedure

1. Any claim by an Eligible Executive with respect to eligibility, participation, contributions, benefits or other aspects of the operation of the Plan shall be made in writing to a person designated by the Committee from time to time for such purpose. If the designated person receiving a claim believes, following consultation with the Chairman of the Committee, that the claim should be denied, he or she shall notify the Eligible Executive in writing of the denial of the claim within ninety (90) days after his or her receipt thereof. This period may be extended an additional ninety (90) days in special circumstances and, in such event, the Eligible Executive shall be notified in writing of the extension, the special circumstances requiring the extension of time and the date by which the Committee expects to make a determination with respect to the claim. If the extension is required due to the Eligible Executive's failure to submit information necessary to decide the claim, the period for making the determination will be tolled from the date on which the extension notice is sent until the date on which the Eligible Executive responds to the Plan's request for information.

2. If a claim is denied in whole or in part, or any adverse benefit determination is made with respect to the claim, the Eligible Executive will be provided with a written notice setting forth (a) the specific reason or reasons for the denial making reference to the pertinent provisions of the Plan or of Plan documents on which the denial is based, (b) a description of any additional material or information necessary to perfect or evaluate the claim, and explain why such material or information, if any, is necessary, and (c) inform the Eligible Executive of his or her right, pursuant to Paragraph A(1) of this Appendix, to request review of the decision. The notice shall also provide an explanation of the Plan's claims review procedure and the time limits applicable to such procedure, as well as a statement of the Eligible Executive's right to bring a civil action under Section 502(a) of ERISA following an adverse benefit determination on review. If an Eligible Executive is not notified (of the denial or an extension) within ninety (90) days from the date the Eligible Executive notifies the Plan Administrator, the Eligible Executive may request a review of the application as if the claim had been denied.

3. An Eligible Executive may appeal the denial of a claim by submitting a written request for review to the Committee, within sixty (60) days after written notification of denial is received. Such period may be extended by the Committee for good cause shown. The claim will then be reviewed by the Committee. In connection with this appeal, the Eligible Executive (or his or her duly authorized representative) may (a) be provided, upon written request and free of charge, with reasonable access to (and copies of) all documents, records, and other information relevant to the claim; and (b) submit to the Committee written comments, documents, records, and other information related to the claim. If the Committee deems it appropriate, it may hold a hearing as to a claim. If a hearing is held, the Eligible Executive shall be entitled to be represented by counsel.

4. The review by the Committee will take into account all comments, documents, records, and other information the Eligible Executive submits relating to the claim. The Committee will make a final written decision on a claim review, in most cases within sixty (60) days after receipt of a request for a review. In some cases, the claim may take more time to review, and an additional processing period of up to sixty (60) days may be required. If that happens, the Eligible Executive will receive a written notice of that fact, which will also indicate the special circumstances requiring the extension of time and the date by which the Committee expects to make a determination with respect to the claim. If the extension is required due to the Eligible Executive's failure to submit information necessary to decide the claim, the period for making the determination will be tolled from the date on which the extension notice is sent to the Eligible Executive until the date on which the Eligible Executive responds to the Plan's request for information.

5. The Committee decision on the claim for review will be communicated to the Eligible Executive in writing. If an adverse benefit determination is made with respect to the claim, the notice will include (a) the specific reason(s) for any adverse benefit determination, with references to the specific Plan provisions on which the determination is based; (b) a statement that the Eligible Executive is entitled to receive, upon request and free of charge, reasonable access to (and copies of) all documents, records and other information relevant to the claim; and (c) a statement of the Eligible Executive's right to bring a civil action under Section 502(a) of ERISA. An Eligible Executive may not start a lawsuit to obtain benefits until after he or she has requested a review and a final decision has been reached on review, or until the appropriate time frame described above has elapsed since the Eligible Executive filed a request for review and you have not received a final decision or notice that an extension will be necessary to reach a final decision. The law also permits the Eligible Executive to pursue his or her remedies under section 502(a) of ERISA without exhausting these appeal procedures if the Plan has failed to follow them.

B. Plan Interpretation and Benefit Determination

1. The Committee (or, where applicable, any duly authorized delegee of the Committee) shall have the exclusive right, power, and authority, in its sole and absolute discretion, to administer, apply and interpret the Plan and any other documents, and to decide all factual and legal matters arising in connection with the operation or administration of the Plan.

2. Without limiting the generality of the foregoing paragraph, the Committee (or, where applicable, any duly authorized delegee of the Committee) shall have the sole and absolute discretionary authority to:

(a) take all actions and make all decisions (including factual decisions) with respect to the eligibility for, and the amount of, benefits payable under the Plan;

(b) formulate, interpret and apply rules, regulations and policies necessary to administer the Plan;

(c) decide questions, including legal or factual questions, relating to the calculation and payment of benefits, and all other determinations made, under the Plan;

(d) resolve and/or clarify any factual or other ambiguities, inconsistencies and omissions arising under this Plan or other Plan documents; and

(e) process, and approve or deny, benefit claims and rule on any benefit exclusions.

All determinations made by the Committee (or, where applicable, any duly authorized delegee of the Committee) with respect to any matter arising under the Plan shall be final and binding on the Company, Eligible Executive, beneficiary, and all other parties affected thereby. Notwithstanding the foregoing, all decisions of the Committee after a Change in Control shall be reviewable on a *de novo* basis by an arbitrator or court, as applicable.

Exhibit 12.1

Regeneron Pharmaceuticals, Inc.
Computation of Ratio of Earnings to Combined Fixed Charges
(Dollars in thousands)

	2004	2005	2006	2007	2008 (B)
Earnings:					
Income (loss) from continuing operations before income (loss) from equity investee	$41,565	$(95,456)	$(103,150)	$(105,600)	$ (82,710)
Fixed charges	14,060	13,687	13,643	13,708	$ 11,261
Amortization of capitalized interest	78	78	73	23	20
Interest capitalized	-	-	-	-	-
Adjusted earnings	$55,703	$(81,691)	$ (89,434)	$ (91,869)	$ (71,429)
Fixed charges:					
Interest expense	$12,175	$ 12,046	$ 12,043	$ 12,043	$ 7,752
Interest capitalized	-	-	-	-	-
Assumed interest component of rental charges	1,885	1,641	1,600	1,665	3,509
Total fixed charges	$14,060	$ 13,687	$ 13,643	$ 13,708	$ 11,261
Ratio of earnings to fixed charges	3.96	(A)	(A)	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2005, 2006, 2007, and 2008 the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

(B) During the year ended December 31, 2008, the registrant repurchased $82.5 million and repaid the remaining $117.5 million of its convertible senior subordinate notes. As of December 31, 2008, the registrant therefore does not have any registered debt outstanding.

	2005	2006	2007	2008 (B)
Coverage deficiency	$95,378	$103,077	$105,577	$82,690

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-50480, 333-85330, 333-97176, 333-33891, 333-80663, 333-61132, 333-97375, 333-119257 and 333-151941) and on Form S-3 (No. 333-121225) of Regeneron Pharmaceuticals, Inc., of our report dated February 26, 2009 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP

New York, New York
February 26, 2009

Exhibit 31.1

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2009

By: /s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 31.2

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2009

By: /s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and Assistant
Secretary

Exhibit 32

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ LEONARD S. SCHLEIFER

Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
February 26, 2009

/s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Chief Financial Officer
February 26, 2009

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-K

Filing Date: 2/17/2011

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2010

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**13-3444607**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No)*
777 Old Saw Mill River Road, Tarrytown, NewYork	**10591-6707**
(Address of principal executive offices)	*(Zip code)*

(914) 347-7000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**NASDAQ Global Select Market**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $1,726,149,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2010, the last trading day of the registrant's most recently completed second fiscal quarter.

The number of shares outstanding of each of the registrant's classes of common stock as of February 11, 2011:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	2,182,036
Common Stock, $.001 par value	87,777,008

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2011 Annual Meeting of Shareholders are incorporated by reference into Part III of this

Form 10-K. Exhibit index is located on pages 67 to 71 of this filing.

PART I

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the nature, timing, and possible success and therapeutic applications of our product candidates and research programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates, the commercial success of our marketed product, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have 11 product candidates in clinical development, including three that are in late-stage, (Phase 3). All of these product candidates were discovered in our research laboratories. Our late-stage programs are VEGF Trap-Eye (aflibercept ophthalmic solution), which is being developed using intraocular delivery for the treatment of serious eye diseases; ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs include the following fully human antibodies, which are being developed in collaboration with sanofi-aventis:

- REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9) for low-density lipoprotein (LDL) cholesterol reduction;
- REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and ankylosing spondylitis;
- REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis and asthma;
- REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology,
- REGN910, an antibody to Angiopoietin-2 (ANG2), another novel angiogenesis target, which is being developed in oncology;
- REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain (currently on clinical hold); and
- REGN728 and REGN846, two antibodies in clinical development against undisclosed targets.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, to combine that foundation with our clinical development and manufacturing capabilities, and to continue to expand our commercialization capabilities in anticipation of possible regulatory approval and launch of one or more of our late-stage product candidates. Our long-term objective is to build a successful, integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3653

Samsung Bioepis Exhibit 1017, pg. 3653

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*®. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® – CAPS

Net product sales of ARCALYST® in 2010 were $25.3 million, which included $20.5 million of ARCALYST® net product sales made in 2010 and $4.8 million of previously deferred net product sales, as described below under Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations." In 2009, we recognized $18.4 million of ARCALYST® net product sales.

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST® is available for prescription in the United States for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We, together with our ex-U.S. collaborator Bayer HealthCare LLC, are evaluating VEGF Trap-Eye in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), and choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia. We and Bayer HealthCare conducted a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME) and are discussing plans to initiate Phase 3 studies in DME. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), compared VEGF Trap-Eye and Lucentis® (ranibizumab injection), a registered trademark of Genentech, Inc. Lucentis® is an anti-angiogenic agent approved for use and the current standard of care in wet AMD. VIEW 1 was conducted in North America and VIEW 2 was conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials both evaluated VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly loading doses), compared with Lucentis® dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents is being evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks.

The primary endpoint of these non-inferiority studies was the proportion of patients treated with VEGF Trap-Eye who maintain visual acuity at the end of one year compared to patients dosed monthly with Lucentis®. Visual acuity is defined as the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, a standard research tool for measuring visual acuity. Maintenance of vision is defined as losing

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3654

Samsung Bioepis Exhibit 1017, pg. 3654

fewer than three lines (equivalent to 15 letters) on the ETDRS chart. Secondary endpoints included the mean change from baseline in visual acuity as measured by ETDRS, the proportion of patients who gained at least 15 letters of vision at week 52, and the amount of fluid under the retina.

We and Bayer HealthCare announced week 52 results from the VIEW 1 and VIEW 2 studies in November 2010. In these studies, all regimens of VEGF Trap-Eye, including VEGF Trap-Eye dosed every two months, successfully met the primary endpoint of statistical non-inferiority compared to Lucentis® dosed every month. In the North American VIEW 1 study, 96% of patients receiving VEGF Trap-Eye 0.5 mg monthly, 95% of patients receiving VEGF Trap-Eye 2.0 mg monthly, and 95% of patients receiving VEGF Trap-Eye 2.0 mg every two months achieved maintenance of vision compared to 94% of patients receiving Lucentis® 0.5 mg dosed every month. In the international VIEW 2 study, 96% of patients receiving VEGF Trap-Eye 0.5 mg monthly, 96% of patients receiving VEGF Trap-Eye 2.0 mg monthly, and 96% of patients receiving VEGF Trap-Eye 2.0 mg every two months achieved maintenance of vision compared to 94% of patients receiving Lucentis® 0.5 mg dosed every month.

A generally favorable safety profile was observed for both VEGF Trap-Eye and Lucentis®. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD; the most frequently reported events were falls, pneumonia, myocardial infarction, atrial fibrillation, breast cancer, and acute coronary syndrome. There were no notable differences among the study arms.

Based on these positive results, we plan to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In addition, Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe.

VEGF Trap-Eye is also in Phase 3 development for the treatment of CRVO, another cause of visual impairment. We are leading the COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study, and Bayer HealthCare is leading the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study. Patients in both studies receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2.0 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients are dosed on a PRN basis for another six months. All patients are eligible for rescue laser treatment.

We and Bayer HealthCare announced in December 2010 that in the COPERNICUS study, VEGF Trap-Eye met the primary endpoint of a statistically significant improvement in visual acuity at six months compared to sham injections. In this trial, 56.1% of patients receiving VEGF Trap-Eye gained at least 15 letters of vision from baseline, compared to 12.3% of patients receiving sham injections ($p<0.0001$). Patients receiving VEGF Trap-Eye on average gained 17.3 letters of vision, compared to a mean loss of 4.0 letters with sham injections ($p<0.001$), a secondary endpoint.

In the COPERNICUS study, VEGF Trap-Eye was generally well tolerated. The most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were uncommon (3.5%) and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. There were no deaths among the 114 patients treated with VEGF Trap-Eye and two (2.7%) in the 73 patients treated with sham injections.

GALILEO study data are expected in the first half of 2011.

The Phase 2 DME study, known as DA VINCI (DME And VEGF Trap-Eye: INvestigation of Clinical Impact), was a double-masked, randomized, controlled trial that evaluated four different dosing regimens of VEGF Trap-Eye versus focal laser treatment. In February 2010, we and Bayer HealthCare announced that treatment with VEGF Trap-Eye demonstrated a statistically significant improvement in visual acuity compared to focal laser therapy at 24 weeks, the primary endpoint of the study. Visual acuity was measured by the mean number of letters gained.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3655

Samsung Bioepis Exhibit 1017, pg. 3655

Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 ($p< 0.01$ for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported. The adverse events reported were those typically associated with intravitreal injections or the underlying disease.

In December 2010, we and Bayer HealthCare reported that the mean visual acuity gains seen in the DA VINCI study at 24 weeks were maintained or numerically improved up to completion of the study at week 52 in all VEGF Trap-Eye study groups, including the group receiving a 2.0 mg dose every two months. At week 52, all VEGF Trap-Eye dose groups reported mean gains in visual acuity of 9.7 to 13.1 letters, compared to a mean loss of 1.3 letters for patients receiving focal laser therapy ($p<0.01$ for each VEGF Trap-Eye dose group versus focal laser). VEGF Trap-Eye was generally well tolerated during the study and no patients experienced ocular drug-related serious adverse events. There were no patients with non-ocular serious adverse events judged by investigators to be drug-related during the first six months of the study and one in the second six months. The most common adverse events reported were those typically associated with intravitreal injections or the underlying disease. The most frequent ocular adverse events reported among patients receiving VEGF Trap-Eye were conjunctival hemorrhage, eye pain, ocular redness (hyperemia), and increased intraocular pressure. The incidence of non-ocular serious adverse events was generally well balanced between all treatment arms. There were six deaths (3.4%) among the 175 patients treated with VEGF Trap-Eye and one (2.3%) in the 44 patients treated with focal laser over 12 months. Based on these positive results, Regeneron and Bayer HealthCare are discussing plans to initiate Phase 3 studies of VEGF Trap-Eye in DME.

In January 2011, we and Bayer HealthCare initiated a new Phase 3 clinical trial in Asia in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of VEGF Trap-Eye in patients with CNV of the retina as a result of pathologic myopia. The study, which will enroll approximately 250 patients, has started in Japan and is scheduled to run until June 2013.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We have received $60 million in development milestone payments and can earn up to $50 million in future milestone payments related to marketing approvals of VEGF Trap-Eye in major market countries outside the United States. We can also earn up to $135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

2. ARCALYST® – Inflammatory Diseases

ARCALYST® is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly allopurinol, is prescribed to eliminate the urate crystals and prevent them from reforming. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We are conducting a Phase 3 clinical development program with ARCALYST® in gout patients initiating uric acid-lowering therapy. The program currently consists of PRE-SURGE 1 (PREvention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, and RE-SURGE (REview of Safety Utilizing Rilonacept in Gout Exacerbations), each of which are described below.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3656

Samsung Bioepis Exhibit 1017, pg. 3656

In June 2010, we announced that results from PRE-SURGE 1, a North America-based double-blind, placebo-controlled study, showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period. Patients initiating uric acid-lowering therapy who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, $p<0.0001$). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, $p<0.0001$).

All secondary endpoints of the study were highly positive ($p<0.001$ vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88% (3.7% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo, $p<0.0001$). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST® 160 mg, 18.8% with ARCALYST® 80 mg, and 46.8% with placebo, $p<0.001$).

A total of 241 patients were randomized in PRE-SURGE 1. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Adverse events that occurred at a frequency of at least 5% in any study group were: injection site reaction (19.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 1.3% with placebo), upper respiratory tract infection (9.9% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 7.6% with placebo), lower respiratory tract infection (0% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 2.5% with placebo), musculoskeletal pain/discomfort (6.2% with ARCALYST® 160 mg, 7.5% with ARCALYST® 80 mg, and 8.9% with placebo), and headache, (3.7% with ARCALYST® 160 mg, 6.3% with ARCALYST® 80 mg, and 1.3% with placebo).

In addition, in June 2010, we reported results from a placebo-controlled, Phase 3 study evaluating pain in patients presenting with an acute gout flare. The results of this study showed that there was no significant benefit from combining ARCALYST® with indomethacin (a non-steroidal anti-inflammatory drug (NSAID) considered the standard of care), as measured by the primary study endpoint, which was the average intensity of gout pain from 24 to 72 hours after initiation of treatment.

There are two ongoing studies in the Phase 3 program with ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy. The global PRE-SURGE 2 study, which has a similar trial design as PRE-SURGE 1, is evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. The global RE-SURGE study is evaluating the safety of ARCALYST® versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. PRE-SURGE 2 and RE-SURGE are fully enrolled, and we expect to have initial data from both studies during the first quarter of 2011. We own worldwide rights to ARCALYST®.

3. Aflibercept – Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A), VEGF-B, and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are conducting three randomized, double-blind Phase 3 trials, all of which are fully enrolled, that are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (VELOUR) is evaluating aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd-line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel/prednisone. In addition, a Phase 2 study (AFFIRM) of aflibercept in 1st-line metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin) is also fully enrolled.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3657

Samsung Bioepis Exhibit 1017, pg. 3657

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a pre-specified number of events have occurred in each trial. In September 2010, we and sanofi-aventis announced that, following a planned interim analysis, the VELOUR study's IDMC recommended that the VELOUR study continue to completion as planned, with no modifications due to efficacy or safety concerns. Both sanofi-aventis and our management and staff remain blinded to the interim study results. Final results from the VITAL and VELOUR studies are anticipated in the first half of 2011. Based on projected event rates, an interim analysis of the VENICE study is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012. Initial data from the AFFIRM study are anticipated in the second half of 2011.

Aflibercept Collaboration with sanofi-aventis

We and sanofi-aventis globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

4. REGN727 (PCSK9 Antibody) for LDL cholesterol reduction

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 is a naturally occurring secreted protein that also modulates LDL cholesterol levels through its interaction with the LDL receptor. In a landmark study published in the *New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL cholesterol, but also a significant reduction in the risk of coronary heart disease. We used our *VelocImmune®* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to robustly lower LDL cholesterol.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from this Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. No serious adverse events and no dose limiting toxicities have been reported. Dose escalation is ongoing in both studies.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested at that time, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean additional reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities were reported. Dose escalation in this study is ongoing. In early 2011, we initiated Phase 2 studies of REGN727 in patients with hypercholesterolemia. REGN727 is being developed in collaboration with sanofi-aventis.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3658

Samsung Bioepis Exhibit 1017, pg. 3658

5. REGN88 (IL-6R Antibody) for inflammatory diseases

IL-6 is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to IL-6R, Actemra® (tocilizumab), a registered trademark of Genentech, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune®* technology that has completed Phase 1 studies, the results of which were presented at the annual meetings of the European League Against Rheumatism (EULAR) in June 2010 and the American College of Rheumatology in October 2010. REGN88 was well tolerated by patients with rheumatoid arthritis, and no dose-limiting toxicities were reported. Treatment with REGN88 resulted in dose-related reductions in biomarkers of inflammation. REGN88 is currently in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients, and initial Phase 2 results are expected in 2011. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN668 (IL-4R Antibody) for allergic and immune conditions

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis.

REGN668 is a fully human monoclonal antibody generated using our *VelocImmune®* technology that is designed to bind to IL-4R. A Phase 1 trial of REGN668 in healthy volunteers has been completed. A Phase 1b study in patients with atopic dermatitis is underway and a Phase 2 study in asthma is planned. REGN668 is being developed in collaboration with sanofi-aventis.

7. REGN421 (Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Dll4, inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune®* technology. REGN421, which is being developed in collaboration with sanofi-aventis, is in Phase 1 clinical development.

8. REGN910 (ANG2 Antibody) for oncology

In the fourth quarter of 2010, we initiated a phase 1 study in the oncology setting of REGN910, an antibody that specifically blocks ANG2. The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, ANG2 is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. REGN910 is being developed for cancer indications in collaboration with sanofi-aventis.

9. REGN475 (NGF Antibody) for pain

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune®* technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF. REGN475 is being developed in collaboration with sanofi-aventis.

In May 2010, we announced an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3659

Samsung Bioepis Exhibit 1017, pg. 3659

The primary endpoint of this study was safety, and REGN475 was generally well tolerated through 16 weeks. Serious treatment emergent adverse events were rare and balanced between placebo and drug arms with three events (5.5%) in the placebo group and four events (2.5%) in the combined REGN475 groups. The most frequent adverse events reported among patients receiving REGN475 included sensory abnormalities, arthralgias, hyper/hypo-reflexia, peripheral edema, and injection site reactions. The types and frequencies of adverse events reported were similar to those previously reported from other investigational studies involving an anti-NGF antibody.

In the first interim efficacy analysis, REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 8 weeks following a single intravenous infusion ($p<0.01$). In July 2010, we reported that REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 16 weeks following a second intravenous infusion at week 8 ($p<0.01$). Pain was measured by the Numeric Rating Scale (NRS), as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) pain and function subscales.

Analysis of efficacy data from a Phase 2 trial in the acute setting of nerve root compression induced pain (acute sciatica) suggested that REGN475 therapy would not be effective in that setting. Studies in burn pain, vertebral compression fracture, and pancreatitis pain have been terminated due to low enrollment.

In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients. REGN475 is being developed in collaboration with sanofi-aventis.

10. REGN728 and REGN846

In the fourth quarter of 2010, clinical trials began with two additional antibodies that are part of the sanofi-aventis collaboration, REGN728 and REGN846. The targets of these antibodies have not been disclosed.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite*™ is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuite™

VelociSuite™ consists of *VelocImmune®, VelociGene®, VelociMouse®, and VelociMab®* The *VelocImmune®* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune®* was generated by exploiting our *VelociGene®* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune®* mice can be

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3660

Samsung Bioepis Exhibit 1017, pg. 3660

used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune*® and our entire *VelociSuite*™ offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune*® technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene*® platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knockout models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, *VelociGene*® offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene*® allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse*® technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse*® technology are suitable for direct phenotyping or other studies. We have also developed our *VelociMab*® platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune*® human monoclonal antibodies.

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. In connection with the execution of the discovery agreement in 2007, we received a non-refundable, up-front payment of $85.0 million from sanofi-aventis. Pursuant to the collaboration, sanofi-aventis is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified through discovery research under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with sanofi-aventis generally funding these costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3661

Samsung Bioepis Exhibit 1017, pg. 3661

Under the amended discovery agreement, sanofi-aventis agreed to fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria were not satisfied. Sanofi-aventis has an option to extend the discovery program for up to an additional three years after 2017 for further antibody development and preclinical activities. Pursuant to the collaboration, sanofi-aventis is also obligated to fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities.

In 2010, as we scaled up our capacity to conduct antibody discovery activities, sanofi-aventis funded $137.7 million of our preclinical research under the expanded collaboration. The balance between that amount and $160 million, or $22.3 million, has been added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement. During 2010, sanofi-aventis also funded $138.3 million of our costs for clinical development of antibodies under the license agreement.

From the collaboration's inception in November 2007 through December 31, 2010, sanofi-aventis has funded a total of $312.7 million of our costs under the discovery agreement and a total of $263.0 million of our development costs under the license agreement, or a total of $575.7 million in funding for our antibody research and development activities during this approximate three-year period.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Under this agreement, sanofi-aventis is required to pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

AstraZeneca UK Limited. In February 2007, we entered into a six-year, non-exclusive license agreement with AstraZeneca UK Limited to allow AstraZeneca to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million annual, non-refundable payment to us in each of the first quarters of 2007, 2008, 2009, and 2010. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement, effective in February 2011, thereby canceling its obligation to make either of the final two annual payments. We remain entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by MedImmune using our *VelocImmune®* technology.

Astellas Pharma Inc. In March 2007, we entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to us in each of the second quarters of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010. In addition, Astellas will make a $130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune®* technology.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis Pharma AG (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion. Canakinumab is marketed for the treatment of CAPS, has completed Phase 3 development for gout, and is in earlier stage development for atherosclerosis and other inflammatory diseases. While our royalties under this agreement

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3662

Samsung Bioepis Exhibit 1017, pg. 3662

could be significant if canakinumab is approved and successfully commercialized for additional disease indications, to date these royalties have been minimal. Accordingly, we are unable to predict whether these royalties will ever contribute materially to our results of operations or financial condition.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received $21.6 million from the grant's inception through December 31, 2010 and are entitled to receive an additional $3.7 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

Sales and Marketing

We have established a small commercial organization to support sales of ARCALYST® for the treatment of CAPS in the United States. We have no sales or distribution personnel and distribute the product through third party service providers. We currently have no sales, marketing, commercial, or distribution organization outside the United States. We are currently expanding our commercial capabilities and increasing the number of commercial personnel in preparation for the potential commercialization of VEGF Trap-Eye and our other late-stage product candidates.

Manufacturing

Our manufacturing facilities are located in Rensselaer, New York and consist of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space. We currently have approximately 54,000 liters of cell culture capacity at these facilities. At December 31, 2010, we employed 356 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2010.

Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the good manufacturing practice (GMP) regulations of the health authority. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies. If our manufacturing facilities fail to comply with FDA and other regulatory requirements, we will be required to suspend manufacturing. This would likely have a material adverse effect on our financial condition, results of operations, and cash flow.

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies (see Item 1A. "Risk Factors – Risks Related to Commercialization of Products – *Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for and may be marketing products with a similar mechanism of action, or may enter the marketplace with better or lower cost drugs.*"). Our competitors include Genentech/Roche, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Eli Lilly and Company, Abbott Laboratories, sanofi-aventis, Merck & Co., Inc., Amgen Inc., AstraZeneca, BristolMyersSquibb, Johnson and Johnson, GlaxoSmithKline, and others. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Competition from smaller competitors may also be or become more significant if those competitors acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we are able to commercialize additional product candidates, one or more of our competitors may have brought a competitive product to market earlier than us or may have obtained

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3663

Samsung Bioepis Exhibit 1017, pg. 3663

or obtain patent protection that dominates or adversely affects our activities or products. Our ability to compete will depend, to a great extent, on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

ARCALYST®. In 2009, Novartis received regulatory approval in the U.S. and Europe for canakinumab, a fully human anti-interleukin-IL1ß antibody, for the treatment of CAPS. In January 2011, Novartis announced that it had submitted an application to the EMA for approval of canakinumab in gout. Novartis has also announced that it plans to submit to the FDA in the first quarter of 2011 an application for approval of canakinumab in gout. Canakinumab is also in development for atherosclerosis and a number of other inflammatory diseases. In addition, there are both small molecules and antibodies in development by other third parties that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Xoma Ltd., in collaboration with Servier, is developing an antibody to IL-1, and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. These drug candidates could offer competitive advantages over ARCALYST®. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST® for CAPS and delay or impair our ability to commercialize ARCALYST® for indications other than CAPS.

VEGF Trap-Eye. The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of wet AMD, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following retinal vein occlusion (RVO). Lucentis® was approved by the European Medicines Agency (EMA) for wet AMD in January 2007 and for the treatment of DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors as well as use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, DME, and RVO, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin® (bevacizumab). The relatively low cost of therapy with Avastin® in patients with wet AMD presents a significant competitive challenge in this indication. The National Eye Institute (NEI) initiated a Phase 3 trial to compare Lucentis® to Avastin® in the treatment of wet AMD. Data from this NEI study are expected to be published in 2011. Avastin® is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other areas.

Aflibercept. Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to aflibercept in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate.

In particular, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and a number of pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Pfizer, Onyx (together with its partner Bayer Healthcare), and GlaxoSmithKline are selling and marketing oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors.

Monoclonal Antibodies. Our early-stage clinical candidates in development are all fully human monoclonal antibodies which were generated using our *VelocImmune®* technology. Our antibody generation technologies and early-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, AstraZeneca, Amgen, Biogen Idec, Inc., Novartis, Genentech/Roche, Bristol-Myers Squib, Abbott, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences. As noted above, AstraZeneca and Astellas have licensed our *VelocImmune®* technology as part of their internal antibody development programs.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3664

Samsung Bioepis Exhibit 1017, pg. 3664

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor Ortho Biotech, Inc. and Bristol-Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, Inc., has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against IL-4 in clinical development. Amgen previously had an antibody against IL-4R in clinical development for the treatment of asthma. We believe that several companies, including Amgen and Pfizer, have development programs for antibodies against PCSK9. Amgen, Pfizer, and AstraZeneca have development programs underway for antibodies against ANG2.

Other Areas. Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics that are the focus of other research or development programs we are now conducting. These competitors include Amgen and Genentech, as well as many others. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our operations or future prospects.

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties or other consideration for use of their technology. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see Item 1A. "Risk Factors – Risks Related to Intellectual Property – *We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.*"). Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. As of December 31, 2010, we held an ownership interest in a total of approximately 170 issued patents in the United States and approximately 590 issued patents in foreign countries with respect to our products and technologies. In addition, we hold an ownership interest in hundreds of patent applications in the United States and foreign countries.

Our patent portfolio includes granted patents and pending patent applications covering our *VelociSuite*™ technologies, including our *VelocImmune*® mouse platform which produces fully human monoclonal antibodies. Our issued patents covering these technologies generally expire between 2020 and 2030. However, we continue to file patent applications directed to improvements to these technology platforms.

Our patent portfolio also includes issued patents and pending applications relating to our marketed product, ARCALYST®, and our product candidates in clinical development. These patents cover the proteins and DNA encoding the proteins, manufacturing patents, method of use patents, and pharmaceutical compositions, as well as

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3665

Samsung Bioepis Exhibit 1017, pg. 3665

various methods of using the products. For each of ARCALYST® and our late-stage product candidates, aflibercept and VEGF Trap-Eye, these patents generally expire between 2020 and 2028. However, the projected patent terms may be subject to extension based on potential patent term extensions in countries where such extensions are available.

We also are the nonexclusive licensee of a number of additional patents and patent applications. In July 2008 we entered into an Amended and Restated Non-Exclusive License Agreement with Cellectis S.A. pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to this agreement, we agreed to pay Cellectis a low, single-digit royalty based on any future revenue received by us from any future licenses or sales of our *VelociGene®* or *VelocImmune®* products or services. No royalties are payable to Cellectis on any revenue from commercial sales of antibodies from our *VelocImmune®* technology, including antibodies developed under our collaboration with sanofi-aventis. We also have non-exclusive license agreements with Amgen and other organizations for patent rights related to ARCALYST®. In exchange for these licenses, we pay a mid-single digit royalty on net sales of ARCALYST®.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. The degree of patent protection that will be afforded to our products in the United States and other important commercial markets is uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, and governments in these countries. There is no certainty that our existing patents or others, if obtained, will provide us protection from competition or provide commercial benefit.

Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights is expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties (see Item 1A. "Risk Factors-Risks Related to Intellectual Property – *We may be restricted in our development, manufacturing, and/or commercialization rights by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights").*

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of ARCALYST® and our product candidates (see Item 1A. "Risk Factors – Regulatory and Litigation Risks – *If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.").* All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an IND, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase 3, large-scale clinical trials are conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3666

Samsung Bioepis Exhibit 1017, pg. 3666

candidate are then submitted to the FDA in the form of a BLA for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

Various federal, state, and foreign statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, and other aspects of pharmaceutical product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

In addition to the foregoing, our present and future business will be subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations.

Business Segments

We manage our business as one segment which includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions and the development and commercialization of these discoveries. This segment also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and our grant from the NIH, (ii) ARCALYST® product sales for the treatment of CAPS, (iii) licensing agreements to utilize our *VelocImmune*® technology, and (iv) the supply of specified, ordered research materials using our *VelociGene*® technology platform.

Employees

As of December 31, 2010, we had 1,395 full-time employees, of whom 276 held a Ph.D. and/or M.D., or PharmD degree. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

Available Information

We make available free of charge on or through our Internet website (http://www.regeneron.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3667

Samsung Bioepis Exhibit 1017, pg. 3667

and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through December 31, 2010, we had a cumulative loss of $1.0 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates, and to prepare for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of the product(s). We believe our existing capital resources, including the $174.8 million net proceeds from our October 2010 public offering of Common Stock and the $165.0 million up-front payment we received in August 2010 pursuant to our amended *VelocImmune*® technology license agreement with Astellas Pharma Inc., together with funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. Our expenses may increase for many reasons, including expenses in connection with the potential commercial launch of our products, expenses related to new clinical trials testing ARCALYST® or VEGF Trap-Eye, and expenses related to the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Should we require and be unable to raise sufficient funds to complete the development of our product candidates and also to successfully commercialize our late-stage product candidates if they obtain regulatory approval, we may face delay, reduction or elimination of our research and development or preclinical or clinical programs, and even if regulatory approval is obtained for such product candidates, they may never be successfully launched or become profitable, in which case our business, financial condition, or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of December 31, 2010, cash, cash equivalents, and marketable securities totaled $626.9 million (including $7.5 million of restricted cash and marketable securities) and represented 58% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities. We consider assets

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3668

Samsung Bioepis Exhibit 1017, pg. 3668

classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled $506.8 million at December 31, 2010, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of $2.5 million, $0.1 million, and $0.1 million in 2008, 2009, and 2010, respectively. The current economic environment and the continued volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and ARCALYST® in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd-line metastatic colorectal cancer, 1st-line androgen independent prostate cancer, and 2nd-line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In March 2010, Genentech, Inc. announced that a Phase 3 trial of its VEGF antagonist, Avastin®, in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of aflibercept in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of CRVO. Although we reported positive Phase 3 trial results with VEGF Trap-Eye in wet AMD after one year of treatment, the trial will continue for an additional year and there is a risk that the results from the second year of the study could differ from the previously reported results, and such difference could delay or preclude regulatory approval. We also reported positive results in the first of two Phase 3 trials in the treatment of CRVO. The trial is continuing and there is a risk that the final results could differ from the previously reported results, and such final results could delay or preclude regulatory approval. There is also a risk that the results of the second Phase 3 trial in CRVO may demonstrate different results, and such results could delay or preclude regulatory approval. A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

ARCALYST® is in Phase 3 clinical trials for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Although we reported positive Phase 3 data from one trial in patients with gout initiating uric acid-lowering drug therapy, there is a risk that the results of the other ongoing trials of ARCALYST® in patients initiating

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3669

Samsung Bioepis Exhibit 1017, pg. 3669

uric acid-lowering drug therapy will differ from the previously reported Phase 3 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to GCPs. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of IDMCs. These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating aflibercept as a 1st-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3670

Samsung Bioepis Exhibit 1017, pg. 3670

side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like VEGF Trap-Eye, which can cause injury to the eye and other complications. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), a registered trademark of Biovitrum, Enbrel® (etanercept), a registered trademark of Amgen and Pfizer, and Remicade® (infliximab) a registered trademark of Centocor, ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. Treatment with Kineret®, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® in gout or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

ARCALYST® and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of ARCALYST® were detected in patients with CAPS after treatment with ARCALYST®. Nineteen of 55 subjects (35%) who received ARCALYST® for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and possibly larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3671

Samsung Bioepis Exhibit 1017, pg. 3671

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. We do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications. However, Genentech could seek to initiate a lawsuit or present a counterclaim for patent infringement in the declaratory judgment action we have filed, and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye or uses thereof. Genentech may be motivated to take such action(s) in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. We commenced in November 2010 a lawsuit against Genentech seeking a declaratory judgment that no activities relating to the Regeneron VEGF Trap infringe any valid claim of certain Genentech patents. It is possible that the court may decide to dismiss the action on procedural grounds or reach an adverse determination that would likely materially harm our business by requiring us to seek a license, which may not be available, or precluding the manufacture, further development, or sale of aflibercept or VEGF Trap-Eye, or resulting in a damage award. Similar patent actions may be taken in other countries, which could have similar or other adverse outcomes that would materially harm our business.

We are aware of patents and pending applications owned by Roche that claim antibodies to IL-6R and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to IL-6R, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3672

Samsung Bioepis Exhibit 1017, pg. 3672

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST®, aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS or VEGF Trap-Eye for the treatment of ophthalmologic disease, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST® and EMA approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3673

Samsung Bioepis Exhibit 1017, pg. 3673

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST® or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.

We and our third party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our marketed product and product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by patients who use ARCALYST® that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3674

Samsung Bioepis Exhibit 1017, pg. 3674

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business and financial results and condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states. In addition, as part of the federal Patient Protection and Affordable Care Act, or PPACA, pharmaceutical companies will be required to file reports with the federal government regarding payments made to healthcare professionals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business and financial results and condition.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business and financial results and condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the Public Company Accounting Oversight Board (PCAOB), the SEC and the NASDAQ Global Market, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, such as shareholder approval of executive compensation (so-called "say on pay") and proxy access. On January 25, 2011, the SEC adopted final rules concerning "say on pay". Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3675

Samsung Bioepis Exhibit 1017, pg. 3675

attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2010, which report is included in this Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The PPACA potential regulations easing the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN727, REGN88, REGN668, REGN421, REGN910, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3676

Samsung Bioepis Exhibit 1017, pg. 3676

and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We currently have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3677

Samsung Bioepis Exhibit 1017, pg. 3677

with applicable GMPs, Good Laboratory Practices (GLPs), or GCP Standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST® for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for all our clinical trials or for commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services for our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may also be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

Our ability to manufacture our products may be impaired if any of our manufacturing activities are found to infringe third-party patents.

The ability for us to manufacture our products in our Rensselaer, New York facilities, or to utilize contract manufacturers to produce our products, depends on our ability to operate without infringing the patents or other intellectual property rights of third parties. Other parties may allege that our manufacturing activities infringe patents or other intellectual property rights. A judicial decision in favor of such third parties could preclude such manufacture of our products.

If any of our clinical programs are delayed or discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, or their clinical development is delayed, we may have to absorb one hundred percent of related overhead costs and inefficiencies.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3678

Samsung Bioepis Exhibit 1017, pg. 3678

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York. We would be unable to manufacture these materials if our Rensselaer facilities were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for the manufacture and formulation of ARCALYST® and of our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of ARCALYST® and our product candidates. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® or our product candidates for use in clinical trials or commercial supply, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacture and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST® for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates receive regulatory approval. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy if such products receive regulatory approval. Though we are currently actively pursuing establishing our own sales, marketing, and distribution organization in anticipation of filing for and receiving regulatory approval to market and sell in the United States VEGF Trap-Eye and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy, we may be unsuccessful in doing so, which would harm our business and adversely affect our future prospects.

There may be too few patients with CAPS to profitably commercialize ARCALYST® in this indication.

Our only approved product is ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009, we received European marketing authorization for rilonacept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST® in this indication.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3679

Samsung Bioepis Exhibit 1017, pg. 3679

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for and may be marketing products with a similar mechanism of action or may enter the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer, Onyx Pharmaceuticals (together with its partner Bayer HealthCare), and GlaxoSmithKline are marketing and selling oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin®, and their extensive, ongoing clinical development plan for Avastin® in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis®, for the treatment of wet AMD, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following RVO. Lucentis® was also approved by the EMA for wet AMD in January 2007 and for DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors, as well as siRNAs that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, DME, and RVO, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin®.

The NEI and others are conducting long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD. Data from these trials are expected in 2011. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis®, because doctors and patients have had significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin® in patients with wet AMD presents a significant competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel®, Remicade®, Humira® (adalimumab), a registered trademark of Abbott, and Simponi® (golimumab), a registered trademark of Centocor, and the IL-1 receptor antagonist Kineret®, and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® in other indications, and this is one of the reasons we discontinued the development of ARCALYST® in adult rheumatoid arthritis. In addition, even if ARCALYST® is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients have had significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST®, such as requiring fewer injections.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3680

Samsung Bioepis Exhibit 1017, pg. 3680

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Eli Lilly, Xoma (in collaboration with Servier), and Novartis are each developing antibodies to IL-1 and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. In 2009, Novartis received regulatory approval in the U.S. and Europe for canakinumab, a fully human anti-interleukin-IL1ß antibody, for the treatment of CAPS. Canakinumab is also in development for atherosclerosis and a number of other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, canakinumab is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST®. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST® for CAPS and delay or impair our ability to commercialize ARCALYST® for indications other than CAPS.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. In January 2011, Novartis announced that the results of two Phase 3 studies with canakinumab focused on reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout were positive. In addition, Novartis announced that it had submitted an application to the EMA for approval of canakinumab in gout. Novartis also announced that it plans to submit to the FDA in the first quarter of 2011 an application for approval of canakinumab in gout. Canakinumab is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST® in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other NSAIDs are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs will make it difficult for us to successfully commercialize ARCALYST® in these diseases.

Our early-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune*® technology. Our antibody generation technologies and early-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, AstraZeneca, Amgen, Biogen Idec, Novartis, Genentech/Roche, Bristol-Myers Squib, Abbott, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor Ortho Biotech and Bristol-Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against IL-4 in clinical development. Amgen previously had an antibody against IL-4R in clinical development for the treatment of asthma. We believe that several companies, including Amgen and Pfizer, have development programs for antibodies against PCSK9. Amgen, Pfizer, and AstraZeneca have development programs underway for antibodies against ANG2. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our operations or future prospects.

The successful commercialization of ARCALYST® and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including NSAIDs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3681

Samsung Bioepis Exhibit 1017, pg. 3681

affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. In particular, payers may impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® in the United States for the treatment of a group of rare genetic disorders called CAPS. We have received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST®. Physicians may not prescribe ARCALYST®, and CAPS patients may not be able to afford ARCALYST®, if third party payers do not agree to reimburse the cost of ARCALYST® therapy and this would adversely affect our ability to commercialize ARCALYST® profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the PPACA and a related reconciliation bill were enacted in the U.S. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers, our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material negative effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers and other key members of our senior management team. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. As we prepare for commercialization in the United States of our late-stage

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3682

Samsung Bioepis Exhibit 1017, pg. 3682

product candidates should they receive regulatory approval, we will also be highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2010, our four largest shareholders plus Leonard S. Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 50.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2010. In September 2003, sanofi-aventis (then Aventis Pharmaceuticals Inc.) purchased 2,799,552 newly issued, unregistered shares of our Common Stock, and in December 2007 sanofi-aventis purchased an additional 12 million newly issued, unregistered shares of our Common Stock. Under our investor agreement, as amended, with sanofi-aventis, these shares may not be sold until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. In addition, in October 2010, sanofi-aventis purchased an additional 1,017,401 shares of Common Stock in our underwritten public offering. As of December 31, 2010, sanofi-aventis beneficially owned 15,816,953 shares of our Common Stock, representing approximately 18.1% of the shares of Common Stock then outstanding. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3683

Samsung Bioepis Exhibit 1017, pg. 3683

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2010, holders of Class A Stock held 20.0% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of December 31, 2010:

- our current executive officers and directors beneficially owned 13.1% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2010, and 26.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2010; and

- our four largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 50.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2010. In addition, these five shareholders held 55.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2010.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;

- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;

- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;

- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;

- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3684

Samsung Bioepis Exhibit 1017, pg. 3684

- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, as amended, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. Under our main lease in Tarrytown, New York, as amended, we lease approximately 545,600 square feet of laboratory and office facilities, including approximately 401,600 square feet of space that we currently occupy and approximately 144,000 square feet of additional new space that we expect to occupy in early 2011. The term of the lease will expire in June 2024. The lease contains three renewal options to extend the term of the lease by five years each and early termination options on approximately 316,000 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Monthly lease payments on the new space commenced in January 2011 and charges for utilities, taxes, and operating expenses commenced in January 2010.

In December 2009, we entered into a separate agreement to lease approximately 6,600 square feet of laboratory and office space at our current Tarrytown location. The term of this lease will expire in August 2011 after which time we have the option to include this space in our main Tarrytown lease, as described above.

In October 2008, we entered into an operating sublease for approximately 14,100 square feet of office space in Bridgewater, New Jersey. The term of the lease expires in July 2011.

We own facilities in Rensselaer, New York, consisting of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space.

The following table summarizes information regarding our current real property leases:

Location	Square Footage	Expiration	Current Monthly Base Rental Charges[1]	Renewal Option Available
Tarrytown, New York	545,600	June 2024	$1,767,600	Three 5-year terms
Tarrytown, New York	6,600	August 2011	$ 21,900	Incorporate into main Tarrytown lease
Bridgewater, New Jersey[2]	14,100	July 2011	$ 21,700	None

(1) Excludes additional charges for utilities, real estate taxes, and operating expenses, as defined.

(2) Relates to sublease in Bridgewater, New Jersey, as described above.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3685

Samsung Bioepis Exhibit 1017, pg. 3685

We believe that our existing owned and leased facilities are adequate for ongoing research, development, manufacturing, and administrative activities. In the future, we may lease, operate, or purchase additional facilities in which to conduct expanded research and development and manufacturing activities and support commercial operations.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition. On November 19, 2010, Regeneron filed a complaint against Genentech, Inc. in the United States District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint. The motion is currently pending. We may initiate similar actions in countries outside the United States.

ITEM 4. [REMOVED AND RESERVED]

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3686

Samsung Bioepis Exhibit 1017, pg. 3686

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for our Common Stock as reported by The NASDAQ Global Select Market:

	High	Low
2009		
First Quarter	$20.08	$11.81
Second Quarter	18.42	12.11
Third Quarter	23.49	16.05
Fourth Quarter	24.97	15.02
2010		
First Quarter	$30.51	$23.42
Second Quarter	30.58	22.33
Third Quarter	27.53	20.45
Fourth Quarter	33.91	24.29

As of February 11, 2011, there were 432 shareholders of record of our Common Stock and 39 shareholders of record of our Class A Stock.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

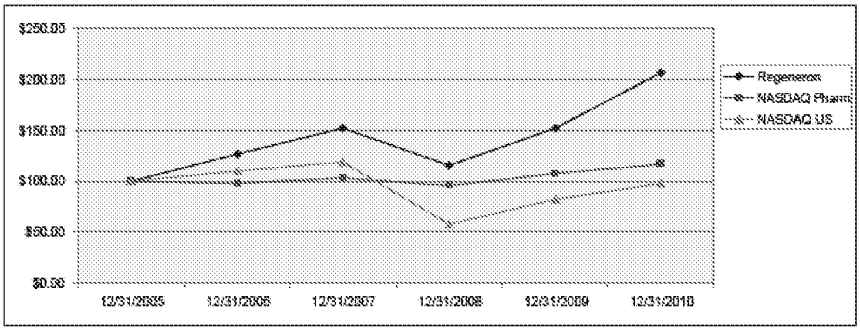
The information under the heading "Equity Compensation Plan Information" in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Annual Report on Form 10-K.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3687

Samsung Bioepis Exhibit 1017, pg. 3687

STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) The NASDAQ Pharmaceuticals Stocks Index and (ii) The NASDAQ Stock Market (U.S.) Index for the period from December 31, 2005 through December 31, 2010. The comparison assumes that $100 was invested on December 31, 2005 in our Common Stock and in each of the foregoing indices. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices. The historical stock price performance of our Common Stock shown in the graph below is not necessarily indicative of future stock price performance.



	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010
Regeneron	$100.00	$126.23	$151.89	$115.47	$152.08	$206.48
NASDAQ Pharm	100.00	97.88	102.94	95.78	107.62	116.66
NASDAQ US	100.00	109.84	119.14	57.41	82.53	97.95

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3688

Samsung Bioepis Exhibit 1017, pg. 3688

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2010, 2009, and 2008 and at December 31, 2010 and 2009 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2007 and 2006 and at December 31, 2008, 2007, and 2006 are derived from our audited financial statements not included in this report.

	Year Ended December 31,				
	2010	2009	2008	2007	2006
	(In thousands, except per share data)				
Statement of Operations Data					
Revenues					
Collaboration revenue	$ 286,725	$314,457	$185,138	$ 87,648	$ 47,763
Technology licensing	40,150	40,013	40,000	28,421	
Contract manufacturing					12,311
Net product sales	25,254	18,364	6,249		
Contract research and other	6,945	6,434	7,070	8,955	3,373
	459,074	379,268	238,457	125,024	63,447
Expenses					
Research and development	489,252	398,762	274,903	202,468	137,064
Contract manufacturing					8,146
Selling, general, and administrative	65,201	52,923	48,880	37,929	25,892
Cost of goods sold	2,093	1,686	923		
	556,546	453,371	324,706	240,397	171,102
Loss from operations	(97,472)	(74,103)	(86,249)	(115,373)	(107,655)
Other income (expense)					
Investment income	2,122	4,488	18,161	20,897	16,548
Interest expense	(9,118)	(2,337)	(7,752)	(12,043)	(12,043)
Loss on early extinguishment of debt			(938)		
	(6,996)	2,151	9,471	8,854	4,505
Net loss before income tax expense and cumulative effect of a change in accounting principle	(104,468)	(71,952)	(76,778)	(106,519)	(103,150)
Income tax (benefit) expense		(4,122)	2,351		
Net loss before cumulative effect of a change in accounting principle	(104,468)	(67,830)	(79,129)	(106,519)	(103,150)
Cumulative effect of a change in accounting principle related to share-based payments					813
Net loss	$(104,468)	$(67,830)	$(79,129)	$(106,519)	$(102,337)
Net loss per share, basic and diluted:					
Net loss before cumulative effect of a change in accounting principle	$ (1.26)	$ (0.85)	$ (1.00)	$ (1.61)	$ (1.78)
Cumulative effect of a change in accounting principle related to share-based payments					0.01
Net loss	$ (1.26)	$ (0.85)	$ (1.00)	$ (1.61)	$ (1.77)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3689

Samsung Bioepis Exhibit 1017, pg. 3689

	At December 31,				
	2010	2009	2008	2007	2006
			(In thousands)		
Balance Sheet Data					
Unrestricted and restricted cash, cash equivalents, and marketable securities (current and non-current)	$ 626,939	$390,010	$527,461	$846,279	$522,859
Total assets	1,089,432	741,302	724,220	957,881	585,090
Notes payable (current and non-current)				200,000	200,000
Facility lease obligations (current and non-current)	160,030	109,022	54,182	21,623	
Capital lease obligations (current and non-current)	2,829				
Stockholders' equity	527,815	396,762	421,514	459,348	216,624

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older.

We have 11 product candidates in clinical development, including three that are in late-stage (Phase 3). All of these product candidates were discovered in our research laboratories. Our late-stage programs are VEGF Trap-Eye, which is being developed using intraocular delivery for the treatment of serious eye diseases; ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment; and aflibercept, which is being developed in oncology in collaboration with sanofi-aventis. Our earlier stage clinical programs include the following fully human antibodies, which are being developed in collaboration with sanofi-aventis:

- REGN727, an antibody to PCSK9 for LDL cholesterol reduction;
- REGN88, an antibody to IL-6R, which is being developed in rheumatoid arthritis and ankylosing spondylitis;
- REGN668, an antibody to IL-4R, which is being developed in atopic dermatitis and asthma;
- REGN421, an antibody to Dll4, a novel angiogenesis target, which is being developed in oncology,
- REGN910, an antibody to ANG2, another novel angiogenesis target, which is being developed in oncology;
- REGN475, an antibody to NGF, which is being developed for the treatment of pain (currently on clinical hold); and
- REGN728 and REGN846, two antibodies in clinical development against undisclosed targets.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3690

Samsung Bioepis Exhibit 1017, pg. 3690

From inception on January 8, 1988 through December 31, 2010, we had a cumulative loss of $1.0 billion, principally related to our research and development activities. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. We plan to submit a BLA to the FDA in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In addition, Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe. If we receive positive Phase 3 clinical trial results, we also expect to file for regulatory approval of ARCALYST® for the prevention of gout flares and of aflibercept in one or more oncology indications. We expect to incur substantial costs to prepare for potential commercialization of these late-stage product candidates and, if one or more of these product candidates receive regulatory approval, to fund the launch of the product(s). Thus, we expect to continue to incur substantial operating losses over at least the next few years related primarily to our research and development and commercialization activities. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, may expand and require additional resources. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the scope and progress of our research and development efforts, the progress of our efforts to commercialize our late-stage product candidates, the timing of certain expenses, and the amount of reimbursement that we receive from collaborators. We cannot predict whether or when our late-stage product candidates will receive regulatory approval or, if such approval is received, whether we will be able to successfully commercialize such product(s), or if we do commercialize such product(s), whether or when they may become profitable.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2010 was 1,249 compared with 980 in 2009 and 810 in 2008. In 2010, 2009, and 2008 our average headcount increased primarily to support our expanded research and development activities in connection with our antibody collaboration with sanofi-aventis. In 2011, we expect our average headcount to increase to approximately 1,600-1,650, primarily to support the further expansion of our research and development activities, especially in connection with our antibody collaboration with sanofi-aventis, and activities in connection with preparing for the potential commercialization of our late-stage product candidates.

Management of cash flow is extremely important as we continue our research and development activities and prepare for potential commercialization of our late-stage product candidates. Our principal sources of cash to-date have been from (i) sales of common equity, both in public offerings and to our collaborators, including sanofi-aventis, (ii) funding from our collaborators and licensees in the form of up-front and milestone payments, technology licensing payments, and payments for our research and development activities, and (iii) a private placement of convertible debt, which was repaid in full during 2008. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. We are reimbursed for a substantial portion of these research and development activities by our collaborators. A significant use of our cash will also be for activities in connection with preparing for the potential commercialization of our late-stage product candidates.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3691

Samsung Bioepis Exhibit 1017, pg. 3691

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2010 and 2011 to date were, and plans for the remainder of 2011 are, as follows:

Clinical Program	2010 and 2011 Events to Date	2011 Plans
VEGF Trap-Eye	• Reported positive 52-week results in the Phase 3 VIEW 1 and VIEW 2 trials in wet AMD • Reported positive six-month results in the Phase 3 COPERNICUS trial in CRVO and completed patient enrollment in the Phase 3 GALILEO trial in CRVO • Reported positive 24-week and 52-week results from the Phase 2 DME trial (DA VINCI) • Initiated a Phase 3 trial in Asia in CNV of the retina as a result of pathologic myopia	• File for regulatory approval of VEGF Trap-Eye in wet AMD in the first half of 2011 • Report initial six-month data from GALILEO in the first half of 2011 • Report two-year data from VIEW 1 and VIEW 2, and one-year data from COPERNICUS in the second half of 2011 • If GALILEO is successful, file for regulatory approval of VEGF Trap-Eye in CRVO
ARCALYST®	• Reported positive results from PRE-SURGE 1 and completed patient enrollment of PRE-SURGE 2 and RE-SURGE. PRE-SURGE 1 and 2 are Phase 3 studies that are evaluating ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy • Reported that in a Phase 3 study evaluating ARCALYST in the treatment of pain during an acute gout flare, there was no significant benefit from combining ARCALYST with an NSAID versus an NSAID alone	• Report data from PRE-SURGE 2 and RE-SURGE in the first quarter of 2011 • If PRE-SURGE 2 and RE-SURGE are successful, file for regulatory approval of ARCALYST® for the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy by mid 2011
Aflibercept (VEGF Trap – Oncology)	• Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer (VITAL), prostate cancer (VENICE), and colorectal cancer (VELOUR) • Completed patient enrollment in a Phase 2 1st-line study in metastatic colorectal cancer (AFFIRM) • An IDMC conducted an interim analysis of VELOUR and recommended that the study continue to completion as planned with no modifications	• Report data from VITAL and VELOUR in the first half of 2011 • An IDMC is expected to conduct an interim analysis of VENICE in mid-2011 • Report data from AFFIRM
REGN727 (PCSK9 Antibody)	• Reported proof-of-concept data from a Phase 1 study for LDL cholesterol reduction • Initiated a Phase 2 program for LDL cholesterol reduction	• Report data from the Phase 2 program for LDL cholesterol reduction

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3692

Samsung Bioepis Exhibit 1017, pg. 3692

Clinical Program	2010 and 2011 Events to Date	2011 Plans
REGN88 (IL-6R Antibody)	• Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis • Initiated a Phase 2 dose-ranging study in ankylosing spondylitis • Reported data from the Phase 1 program in rheumatoid arthritis	• Report initial data in rheumatoid arthritis and in ankylosing spondylitis
REGN668 (IL-4R Antibody)	• Completed a Phase 1 study in healthy volunteers • Initiated a Phase 1b program in atopic dermatitis	• Initiate a Phase 2 program in asthma
REGN421 (Dll4 Antibody)	• Continued patient enrollment in Phase 1 program	• Initiate a Phase 2 program in advanced malignancies
REGN910 (ANG2 Antibody)	• Initiated a Phase 1 study in oncology	
REGN475 (NGF Antibody)	• Reported top-line results from Phase 2 studies in osteoarthritis of the knee and acute sciatica • Phase 2 studies placed on clinical hold in December 2010 by the FDA due to adverse events seen with NGF antibodies under development at other pharmaceutical companies	
REGN728 (target not disclosed)	• Initiated clinical development in an undisclosed indication	
REGN846 (target not disclosed)	• Initiated clinical development in an undisclosed indication	

Critical Accounting Policies and Use of Estimates

A summary of the significant accounting policies that impact us is provided in Note 2 to our Financial Statements, beginning on page F-7. The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- It requires an assumption (or assumptions) regarding a future outcome; and
- Changes in the estimate or the use of different assumptions to prepare the estimate could have a material effect on our results of operations or financial condition.

Management believes the current assumptions used to estimate amounts reflected in our financial statements are appropriate. However, if actual experience differs from the assumptions used in estimating amounts reflected in our financial statements, the resulting changes could have a material adverse effect on our results of operations, and in certain situations, could have a material adverse effect on our liquidity and financial condition. The critical accounting estimates that impact our financial statements are described below.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3693

Samsung Bioepis Exhibit 1017, pg. 3693

Revenue Recognition

Collaboration Revenue

We earn collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize our technology platforms. We currently have collaboration agreements with sanofi-aventis and Bayer HealthCare. The terms of collaboration agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

We enter into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. We may share the costs of research and development activities with our collaborator, such as in our VEGF Trap-Eye collaboration with Bayer HealthCare, or we may be reimbursed for all or a significant portion of the costs of our research and development activities, such as in our aflibercept and antibody collaborations with sanofi-aventis. We record our internal and third-party development costs associated with these collaborations as research and development expenses. When we are entitled to reimbursement of all or a portion of the research and development expenses that we incur under a collaboration, we record those reimbursable amounts as collaboration revenue proportionately as we recognize our expenses. If the collaboration is a cost-sharing arrangement in which both we and our collaborator perform development work and share costs, in periods when our collaborator incurs development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of the collaborator's development expenses that we are obligated to reimburse.

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, our estimated performance periods may change if development programs encounter delays or we and our collaborators decide to expand or contract our clinical plans for a drug candidate in various disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

Product Revenue

Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distributor fees, and other sales-related deductions. We review our estimates of rebates payable each period and record any necessary adjustments in the current period's net product sales.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3694

Samsung Bioepis Exhibit 1017, pg. 3694

Clinical Trial Expenses

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as CROs, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by CROs. CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts with CROs are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue expense on an estimated cost-per-patient basis, based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the years ended December 31, 2010, 2009, or 2008.

Stock-based Employee Compensation

We recognize stock-based compensation expense for grants of stock option awards and restricted stock to employees and non-employee members of our board of directors under our long-term incentive plans based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period.

We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our historical exercise experience with previously issued employee and board of directors option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3695

Samsung Bioepis Exhibit 1017, pg. 3695

The assumptions used in computing the fair value of option awards reflect our best estimates but involve uncertainties related to market and other conditions, many of which are outside of our control. Changes in any of these assumptions may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in future periods.

In addition, we have granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, we estimate that these options will vest, which is based on whether we consider the options' performance conditions to be probable of attainment. Our estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods. Changes in these estimates may materially affect the amount of stock-based compensation that we recognize in future periods related to performance-based options.

Marketable Securities

We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. We consider our marketable securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board (FASB). These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that may be charged against income.

On a quarterly basis, we review our portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. Such factors include the length of time and the extent to which market value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. With respect to debt securities, this review process also includes an evaluation of our intent to sell an individual debt security or our need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of our ability and intent to hold the securities until their full value can be recovered. This review is subjective and requires a high degree of judgment. For example, as a result of our quarterly reviews of our marketable securities portfolio, during 2010, 2009, and 2008 we recorded charges for other-than-temporary impairment of our marketable securities totaling $0.1 million, $0.1 million, and $2.5 million, respectively.

Depreciation of Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. In some situations, the life of the asset may be extended or shortened if circumstances arise that would lead us to believe that the estimated life of the asset has changed. The life of leasehold improvements may change based on the extension of lease contracts with our landlords. Changes in the estimated lives of assets will result in an increase or decrease in the amount of depreciation recognized in future periods. For example, effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, were extended. The effect of this change in estimate was to lower depreciation expense by $4.0 million and to lower our net loss per share by $0.05 for the year ended December 31, 2010.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3696

Samsung Bioepis Exhibit 1017, pg. 3696

Results of Operations

Years Ended December 31, 2010 and 2009

Net Loss

Regeneron reported a net loss of $104.5 million, or $1.26 per share (basic and diluted), for the year ended December 31, 2010, compared to a net loss of $67.8 million, or $0.85 per share (basic and diluted) for 2009. The increase in our net loss in 2010 was principally due to higher research and development expenses, partly offset by higher collaboration revenue in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues in 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	$311.3	$247.2
Bayer HealthCare	75.4	67.3
Total collaboration revenue	386.7	314.5
Technology licensing revenue	40.2	40.0
Net product sales	25.3	18.4
Contract research and other revenue	6.9	6.4
Total revenue	$459.1	$379.3

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earned from sanofi-aventis, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

	Years ended December 31,	
Sanofi-aventis Collaboration Revenue	**2010**	**2009**
(In millions)		
Aflibercept		
Regeneron expense reimbursement	$ 16.5	$ 26.6
Recognition of deferred revenue related to up-front payments	9.9	9.9
Total aflibercept	26.4	36.5
Antibody		
Regeneron expense reimbursement	276.0	198.1
Recognition of deferred revenue related to up-front and other payments	7.3	9.9
Recognition of revenue related to *VelociGene*® agreement	1.6	2.7
Total antibody	284.9	210.7
Total sanofi-aventis collaboration revenue	$311.3	$247.2

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in 2010 compared to 2009, primarily due to lower costs related to internal research activities and manufacturing aflibercept clinical supplies. As of December 31, 2010, $32.6 million of the original $105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of $137.7 million under the discovery agreement and $138.3 million of development costs under the license agreement, compared to $99.8 million and $98.3 million, respectively, in 2009. The higher reimbursement amounts in 2010 compared to 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3697

Samsung Bioepis Exhibit 1017, pg. 3697

Recognition of deferred revenue related to sanofi-aventis' $85.0 million up-front payment decreased in 2010 compared to 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $23.4 million was received or receivable from sanofi-aventis as of December 31, 2010. Revenue related to these payments for such funding from sanofi-aventis is deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the recognition of the original $85.0 million up-front payment. As of December 31, 2010, $79.8 million of the sanofi-aventis payments was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. In 2010 and 2009, we recognized $1.6 million and $2.7 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron VEGF Trap-Eye development expenses, substantive performance milestone payments, and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Years ended December 31,**	
(In millions)	**2010**	**2009**
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$45.5	$37.4
Substantive performance milestone payments	20.0	20.0
Recognition of deferred revenue related to up-front and other milestone payments	9.9	9.9
Total Bayer HealthCare collaboration revenue	$75.4	$67.3

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in 2010 compared to 2009 due to higher internal development activities and higher clinical development costs in connection with our Phase 3 COPERNICUS trial in CRVO. In the fourth quarter of 2010, we earned two $10.0 million substantive milestone payments from Bayer HealthCare for achieving positive 52-week results in the VIEW 1 study and positive 6-month results in the COPERNICUS study. In July 2009, we earned a $20.0 million substantive performance milestone payment from Bayer HealthCare in connection with the dosing of the first patient in the COPERNICUS study. In connection with the recognition of deferred revenue related to the $75.0 million up-front payment and $20.0 million milestone payment received in August 2007, as of December 31, 2010, $47.0 million of these payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments were deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In both 2010 and 2009, we recognized $40.0 million of technology licensing revenue related to these agreements. In addition, in connection with the amendment and extension of our license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and will be recognized as revenue ratably over a seven-year period beginning in mid-2011. As of December 31, 2010, $176.6 million of these technology licensing payments was deferred and will be recognized as revenue in future periods.

Net Product Sales

In 2010 and 2009, we recognized as revenue $25.3 million and $18.4 million, respectively, of ARCALYST® net product sales for which both the right of return no longer existed and rebates could be reasonably estimated. The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3698

Samsung Bioepis Exhibit 1017, pg. 3698

accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower our net loss per share by $0.06 in 2010. At December 31, 2010, there was no deferred revenue related to ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue in 2010 and 2009 included $4.6 million and $5.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $556.5 million in 2010 from $453.4 million in 2009. Our average headcount in 2010 increased to 1,249 from 980 in 2009 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2010 and 2009 included a total of $39.9 million and $31.3 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the year ended December 31, 2010		
Expenses	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
(In millions)			
Research and development	$466.9	$22.3	$489.2
Selling, general, and administrative	47.6	17.6	65.2
Cost of goods sold	2.1		2.1
Total operating expenses	$516.6	$39.9	$556.5

	For the year ended December 31, 2009		
Expenses	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
(In millions)			
Research and development	$380.9	$18.8	$399.8
Selling, general, and administrative	40.4	12.5	52.9
Cost of goods sold	1.7		1.7
Total operating expenses	$422.1	$31.3	$453.4

The increase in total Non-cash Compensation Expense in 2010 was primarily attributable to (i) the recognition of higher expense in 2010 in connection with performance-based stock options that we estimate will vest, (ii) the increase in stock option awards in 2010, due in part to the increase in headcount, and (iii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2009 compared to December 2008.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3699

Samsung Bioepis Exhibit 1017, pg. 3699

Research and Development Expenses

Research and development expenses increased to $489.2 million in 2010 from $398.8 million in 2009. The following table summarizes the major categories of our research and development expenses in 2010 and 2009:

Research and Development Expenses	Year Ended December 31, 2010	2009	Increase (Decrease)
(In millions)			
Payroll and benefits[1]	$131.7	$ 99.9	$31.8
Clinical trial expenses	106.9	111.6	(4.7)
Clinical manufacturing costs[2]	95.6	66.7	28.9
Research and other development costs	53.8	42.3	11.5
Occupancy and other operating costs	52.3	40.6	11.7
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses[3]	48.9	37.7	11.2
Total research and development expenses	$489.2	$398.8	$90.4

(1) Includes $19.3 million and $16.2 million of Non-cash Compensation Expense in 2010 and 2009, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $3.0 million and $2.6 million of Non-cash Compensation Expense in 2010 and 2009, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap- Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® in gout, partly offset by higher costs related to our clinical development programs for VEGF Trap-Eye, principally in connection with our COPERNICUS trial in CRVO. Clinical manufacturing costs increased due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility and higher costs related to manufacturing clinical supplies of monoclonal antibodies, partly offset by lower costs related to manufacturing aflibercept clinical supplies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD which is being conducted by Bayer HealthCare.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3700

Samsung Bioepis Exhibit 1017, pg. 3700

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	Year ended December 31,		Increase
Project Costs	**2010**	**2009**	**(Decrease)**
(In millions)			
ARCALYST®	$ 56.8	$ 67.7	$(10.9)
VEGF Trap-Eye	138.5	109.8	28.7
Aflibercept	13.5	23.3	(9.8)
REGN88	25.0	36.9	(11.9)
REGN727	36.0	21.1	14.9
Other antibody candidates in clinical development	65.5	53.3	12.2
Other research programs & unallocated costs	153.9	86.7	67.2
Total research and development expenses	$489.2	$398.8	$ 90.4

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a BLA must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST® and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3701

Samsung Bioepis Exhibit 1017, pg. 3701

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $65.2 million in 2010 from $52.9 million in 2009 due primarily to increases in compensation expense and recruitment costs, principally in connection with higher headcount in 2010, and an increase in Non-cash Compensation Expense for the reasons described above.

Cost of Goods Sold

Cost of goods sold in 2010 and 2009 was $2.1 million and $1.7 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies. To date, ARCALYST® shipments to our customers have primarily consisted of supplies of inventory manufactured and expensed as research and development costs prior to FDA approval in 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to $2.1 million in 2010 from $4.5 million in 2009, due primarily to lower yields on, and lower average balances of, cash and marketable securities.

Interest expense increased to $9.1 million in 2010 from $2.3 million in 2009. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York.

Income Tax Expense (Benefit)

In 2010, we did not recognize any income tax expense or benefit. In 2009, we recognized a $4.1 million income tax benefit, consisting primarily of (i) $2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allowed us to claim a refund of U.S. federal alternative minimum tax that we paid in 2008, and (ii) $0.7 million resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

Years Ended December 31, 2009 and 2008

Net Loss

Regeneron reported a net loss of $67.8 million, or $0.85 per share (basic and diluted), for the year ended December 31, 2009, compared to a net loss of $79.1 million, or $1.00 per share (basic and diluted) for 2008. The decrease in our net loss in 2009 was principally due to higher collaboration revenue in connection with our antibody collaboration with sanofi-aventis, receipt of a $20.0 million substantive performance milestone payment in connection with our VEGF Trap-Eye collaboration with Bayer HealthCare, and higher ARCALYST® sales, partly offset by higher research and development expenses, as detailed below.

Revenues

Revenues in 2009 and 2008 consist of the following:

(In millions)	2009	2008
Collaboration revenue		
Sanofi-aventis	$247.2	$154.0
Bayer HealthCare	67.3	31.2
Total collaboration revenue	314.5	185.2
Technology licensing revenue	40.0	40.0
Net product sales	18.4	6.3
Contract research and other revenue	6.4	7.0
Total revenue	$379.3	$238.5

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3702

Samsung Bioepis Exhibit 1017, pg. 3702

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earned from sanofi-aventis, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue	Years ended December 31,	
(In millions)	2009	2008
Aflibercept		
Regeneron expense reimbursement	$ 26.6	$ 35.6
Recognition of deferred revenue related to up-front payments	9.9	8.8
Total aflibercept	36.5	44.4
Antibody		
Regeneron expense reimbursement	198.1	97.9
Recognition of deferred revenue related to up-front payment	9.9	10.5
Recognition of revenue related to *VelociGene*® agreement	2.7	1.2
Total antibody	210.7	109.6
Total sanofi-aventis collaboration revenue	$247.2	$154.0

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in 2009 compared to 2008, primarily due to lower costs related to internal research activities and manufacturing aflibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments increased in 2009 compared to 2008 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of December 31, 2009, $42.5 million of the original $105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2009, sanofi-aventis' reimbursement of our antibody expenses consisted of $99.8 million under the discovery agreement and $98.3 million of development costs under the license agreement, compared to $72.2 million and $25.7 million, respectively, in 2008. The higher reimbursement amounts in 2009 compared to 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement. Recognition of deferred revenue related to sanofi-aventis' $85.0 million up-front payment decreased in 2009 compared to 2008 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. As of December 31, 2009, $63.7 million of the original $85.0 million up-front payment was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene*® agreement with sanofi-aventis. In 2009 and 2008, we recognized $2.7 million and $1.2 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	Years ended December 31,	
(In millions)	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$37.4	$18.8
Substantive performance milestone payment	20.0	
Recognition of deferred revenue related to up-front and other milestone payments	9.9	12.4
Total Bayer HealthCare collaboration revenue	$67.3	$31.2

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3703

Samsung Bioepis Exhibit 1017, pg. 3703

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in 2009 compared to 2008. Under the terms of the collaboration, in 2009, all agreed-upon VEGF Trap-Eye development expenses incurred by Regeneron and Bayer HealthCare under a global development plan were shared equally. In 2008, the first $70.0 million of agreed-upon VEGF Trap-Eye development expenses were shared equally, and we were solely responsible for up to the next $30.0 million. During the fourth quarter of 2008, we were solely responsible for most of the collaboration's VEGF Trap-Eye development expenses, which reduced the amount of cost-sharing revenue we earned from Bayer HealthCare in 2008. In addition, cost-sharing revenue increased in 2009, compared to 2008, due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 DA VINCI trial in DME, and COPERNICUS trial in CRVO. In July 2009, we received a $20.0 million substantive performance milestone payment from Bayer HealthCare in connection with our COPERNICUS trial, which was recognized as collaboration revenue. Recognition of deferred revenue related to the up-front and August 2007 milestone payments from Bayer HealthCare decreased in 2009 from 2008 due to an extension of the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of December 31, 2009, $56.8 million of these up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments were deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In both 2009 and 2008, we recognized $40.0 million of technology licensing revenue related to these agreements.

Net Product Sales

In 2009 and 2008, we recognized as revenue $18.4 million and $6.3 million, respectively, of ARCALYST® net product sales for which both the right of return no longer existed and rebates could be reasonably estimated. At December 31, 2009, deferred revenue related to ARCALYST® net product sales totaled $4.8 million.

Contract Research and Other Revenue

Contract research and other revenue in 2009 and 2008 included $5.5 million and $4.9 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $453.4 million in 2009 from $324.7 million in 2008. Our average headcount in 2009 increased to 980 from 810 in 2008 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2009 and 2008 included a total of $31.3 million and $32.5 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the year ended December 31, 2009		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 380.0	$ 18.8	$ 398.8
Selling, general, and administrative	40.4	12.5	52.9
Cost of goods sold	1.7		1.7
Total operating expenses	$ 422.1	$ 31.3	453.4

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3704

Samsung Bioepis Exhibit 1017, pg. 3704

Expenses *(In millions)*	For the year ended December 31, 2008 Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 255.9	$ 19.0	$ 274.9
Selling, general, and administrative	35.4	13.5	48.9
Cost of goods sold	0.9		0.9
Total operating expenses	$ 292.2	$ 32.5	$ 324.7

The decrease in total Non-cash Compensation Expense in 2009 was primarily attributable to the lower fair market value of our Common Stock on the date of our annual employee option grants made in December 2008 as compared to the fair market value of annual employee option grants made in recent years prior to 2008.

Research and Development Expenses

Research and development expenses increased to $398.8 million in 2009 from $274.9 million in 2008. The following table summarizes the major categories of our research and development expenses in 2009 and 2008:

Research and Development Expenses *(In millions)*	Year Ended December 31, 2009	2008	Increase
Payroll and benefits[1]	$ 99.9	$ 81.7	$ 18.2
Clinical trial expenses	111.6	49.3	62.3
Clinical manufacturing costs[2]	66.7	53.8	12.9
Research and other development costs	42.3	29.6	12.7
Occupancy and other operating costs	40.6	30.5	10.1
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses[3]	37.7	30.0	7.7
Total research and development	$398.8	$274.9	$123.9

(1) Includes $16.2 million and $16.7 million of Non-cash Compensation Expense in 2009 and 2008, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $2.6 million and $2.3 million of Non-cash Compensation Expense in 2009 and 2008, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap- Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, DA VINCI trial in DME, and COPERNICUS trial in CRVO, (ii) ARCALYST®, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibody candidates, which are in earlier stage clinical development. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of ARCALYST® and monoclonal antibodies, partly offset by lower costs related to manufacturing aflibercept clinical supplies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3705

Samsung Bioepis Exhibit 1017, pg. 3705

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	Year ended December 31,		Increase
(In millions)	2009	2008	(Decrease)
ARCALYST®	$ 67.7	$ 39.2	$ 28.5
VEGF Trap-Eye	109.8	82.7	27.1
Aflibercept	23.3	32.1	(8.8)
REGN88	36.9	21.4	15.5
Other antibody candidates in clinical development	74.4	27.4	47.0
Other research programs & unallocated costs	86.7	72.1	14.6
Total research and development expenses	$398.8	$274.9	$123.9

For the reasons described above in Results of Operations for the years ended December 31, 2010 and 2009, under the caption "Research and Development Expenses", and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $52.9 million in 2009 from $48.9 million in 2008. In 2009, we incurred (i) higher compensation expense, (ii) higher patent-related costs, (iii) higher facility-related costs due primarily to increases in administrative headcount, and (iv) higher patient assistance costs related to ARCALYST®. These increases were partly offset by (i) lower marketing costs related to ARCALYST®, (ii) a decrease in administrative recruitment costs, and (iii) lower professional fees related to various corporate matters.

Cost of Goods Sold

During 2008, we began recognizing revenue and cost of goods sold from net product sales of ARCALYST®. Cost of goods sold in 2009 and 2008 was $1.7 million and $0.9 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies. In 2009 and 2008, ARCALYST® shipments to our customers consisted of supplies of inventory manufactured and expensed as research and development costs prior to FDA approval in 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to $4.5 million in 2009 from $18.2 million in 2008, due primarily to lower yields on, and lower balances of, cash and marketable securities. In addition, in 2009 and 2008, deterioration in the credit quality of specific marketable securities in our investment portfolio subjected us to the risk of not being able to recover these securities' carrying values. As a result, in 2009 and 2008, we recognized charges of $0.1 million and $2.5 million, respectively, related to these securities, which we considered to be other than temporarily impaired. In 2009 and 2008, these charges were either wholly or partly offset by realized gains of $0.2 million and $1.2 million, respectively, on sales of marketable securities during the year.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3706

Samsung Bioepis Exhibit 1017, pg. 3706

Interest expense decreased to $2.3 million in 2009 from $7.8 million in 2008. Interest expense in 2009 was attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. Interest expense in 2008 related to $200.0 million of 5.5% Convertible Senior Subordinated Notes until they were retired. During the second and third quarters of 2008, we repurchased a total of $82.5 million in principal amount of these convertible notes for $83.3 million. In connection with these repurchases, we recognized a $0.9 million loss on early extinguishment of debt, representing the premium paid on the notes plus related unamortized debt issuance costs. The remaining $117.5 million of convertible notes were repaid in full upon their maturity in October 2008.

Income Tax Expense (Benefit)

In 2009, we recognized a $4.1 million income tax benefit, consisting primarily of (i) $2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allowed us to claim a refund of U.S. federal alternative minimum tax that we paid in 2008, as described below, and (ii) $0.7 million resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

In 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards that would otherwise have expired over the next several years, to offset income for tax purposes. As a result, we incurred and paid income tax expense of $3.1 million, which relates to U.S. federal and New York State alternative minimum taxes and included $0.2 million of interest and penalties. This expense was partly offset by a $0.7 million income tax benefit, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, and our technology licensing agreements, ARCALYST® product revenue, and investment income.

Sources and Uses of Cash for the Years Ended December 31, 2010, 2009, and 2008

At December 31, 2010, we had $626.9 million in cash, cash equivalents, and marketable securities (including $7.5 million of restricted cash and marketable securities) compared with $390.0 million at December 31, 2009 (including $1.6 million of restricted cash) and $527.5 million (including $1.7 million of restricted cash) at December 31, 2008. In October 2010, the Company completed an underwritten public offering of 6,325,000 shares of Common Stock and received net proceeds of $174.8 million. Under the terms of our non-exclusive license agreements with AstraZeneca and Astellas, each company made $20.0 million annual, non-refundable payments to us in each of 2010, 2009, and 2008. In addition, in connection with the July 2010 amendment and extension of our license agreement with Astellas, we received a $165.0 million up-front payment from Astellas in August 2010. We also received, from Bayer HealthCare, a $10.0 million milestone payment in December 2010 in connection with the VIEW 1 study, and a $20.0 million milestone payment in July 2009 in connection with the COPERNICUS study.

Cash Provided by (Used in) Operations

Net cash provided by operations was $96.3 million in 2010, compared with net cash used in operations of $72.2 million in 2009 and $89.1 million in 2008. Our net losses of $104.5 million in 2010, $67.8 million in 2009, and $79.1 million in 2008 included $39.9 million, $31.3 million, and $32.5 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of $19.7 million, $14.2 million, and $11.3 million in 2010, 2009, and 2008, respectively.

At December 31, 2010, accounts receivable increased by $27.5 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis and a $10.0 million milestone payment receivable from Bayer HealthCare, which was earned in December 2010 in connection with the COPERNICUS study. Our deferred revenue at December 31, 2010 increased by $158.2 million, compared to

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3707

Samsung Bioepis Exhibit 1017, pg. 3707

end-of-year 2009, primarily due to (i) the receipt of the $165.0 million up-front payment from Astellas, as described above, which was deferred and will be recognized ratably over the seven-year period commencing in mid-2011 and (ii) sanofi-aventis' funding of $22.9 million of agreed-upon costs incurred by us during 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original $85.0 million up-front payment received from sanofi-aventis. These increases were partly offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities increased $7.6 million at December 31, 2010, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll-related expenses.

At December 31, 2009, accounts receivable increased by $30.4 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Our deferred revenue at December 31, 2009 decreased by $27.5 million, compared to end-of-year 2008, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. Accounts payable, accrued expenses, and other liabilities increased $12.6 million at December 31, 2009, compared to end-of-year 2008, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for clinical-related expenses, which were partly offset by an $8.6 million decrease in the cost-sharing payment due to Bayer HealthCare in connection with our VEGF Trap-Eye collaboration.

At December 31, 2008, accounts receivable increased by $16.9 million, compared to end-of-year 2007, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Our deferred revenue at December 31, 2008 decreased by $26.8 million, compared to end-of-year 2007, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by the deferral of $4.0 million of ARCALYST® net product sales at December 31, 2008.

The majority of our cash expenditures in 2010, 2009, and 2008 were to fund research and development, primarily related to our clinical programs and our preclinical human monoclonal antibody programs. In 2008, we made interest payments totaling $9.3 million on our convertible senior subordinated notes. The convertible notes were repaid in full in October 2008.

Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $434.2 million in 2010, compared with net cash provided by investing activities of $146,000 in 2009 and $30.8 million in 2008. In 2010, purchases of marketable securities exceeded sales or maturities by $335.6 million. In 2009 and 2008, sales or maturities of marketable securities exceeded purchases by $97.4 million and $65.7 million, respectively. Capital expenditures in 2010, 2009, and 2008 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December 2006 Tarrytown, New York lease, as described below.

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $243.3 million in 2010 and $31.4 million in 2009, respectively, and net cash used in financing activities was $192.9 million in 2008. In October 2010, we completed an underwritten public offering of 6,325,000 shares of our Common Stock and received net proceeds of $174.8 million. In addition, proceeds from issuances of our Common Stock in connection with exercises of stock options were $22.0 million in 2010, $8.6 million in 2009, and $7.9 million in 2008. In 2010 and 2009, we received $47.5 million and $23.6 million, respectively, of tenant improvement reimbursements from our landlord in connection with our new Tarrytown facilities, which we are deemed to own in accordance with FASB authoritative guidance. In the second and third quarters of 2008, we repurchased $82.5 million in principal amount of our convertible senior subordinated notes for $83.3 million. The remaining $117.5 million of convertible notes were repaid in full upon their maturity in October 2008.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3708

Samsung Bioepis Exhibit 1017, pg. 3708

Fair Value of Marketable Securities

At December 31, 2010 and 2009, we held marketable securities whose aggregate fair value totaled $513.9 million and $181.3 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	2010		2009	
Investment type	**Fair Value**	**Percent**	**Fair Value**	**Percent**
Unrestricted				
U.S. government agency securities	$ 434.4	85%	$ 29.6	16%
U.S. Treasury securities			80.4	44%
U.S. government-guaranteed corporate bonds	64.0	13%	48.7	27%
Equity securities	3.6	1%	5.4	3%
U.S. government guaranteed collateralized mortgage obligations	2.1		3.7	2%
Corporate bonds			10.3	6%
Other	1.6			
Mortgage-backed securities	1.1		3.2	2%
Total unrestricted marketable securities	506.8	99%	181.3	100%
Restricted				
U.S. government agency securities	7.1	1%		
Total marketable securities	$ 513.9	100%	$ 181.3	100%

In addition, at December 31, 2010 and 2009, we had $113.0 million and $208.7 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

We classify our investments using a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers are Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The Company held one Level 3 marketable security, which had no fair value at December 31, 2010 and 2009, and whose fair value was $0.1 million at December 31, 2008. This Level 3 security was valued using information provided by the Company's investment advisors and other sources, including quoted bid prices which took into consideration the securities' lack of liquidity. During the year ended December 31, 2009, the Company recorded charges for other-than-temporary impairment of this Level 3 marketable security totaling $0.1 million; therefore, as of December 31, 2009, the fair value of this security had been written down to zero. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the years ended December 31, 2010 and 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the years ended December 31, 2010 and 2009.

Our methods for valuing our marketable securities are described in Note 2 to our financial statements included in this Annual Report on Form 10-K. With respect to valuations for pricing our Level 2 marketable securities, we consider quantitative and qualitative factors such as financial conditions and near term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. For valuations that we determine for our Level 3 marketable securities, we regularly monitor these securities and adjust their valuations as deemed appropriate based on the facts and circumstances.

Collaborations with sanofi-aventis

Aflibercept

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. Sanofi-aventis made a non-refundable up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for $45.0 million.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3709

Samsung Bioepis Exhibit 1017, pg. 3709

In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In connection with this amendment, sanofi-aventis made a $25.0 million non-refundable payment to us.

In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a $25.0 million non-refundable up-front payment to us, which was received in January 2006. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

We have agreed to manufacture clinical supplies of aflibercept at our plant in Rensselaer, New York. Sanofi-aventis has agreed to be responsible for providing commercial scale manufacturing capacity for aflibercept.

Under the collaboration agreement, as amended, agreed upon worldwide aflibercept development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to $7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs. Since inception of the collaboration agreement through December 31, 2010, we and sanofi-aventis have incurred $707.3 million in agreed upon development expenses related to aflibercept. Currently, multiple clinical studies to evaluate aflibercept as both a single agent and in combination with other therapies in various cancer indications are ongoing.

Sanofi-aventis funded $16.5 million, $26.6 million, and $35.6 million, respectively, of our aflibercept development costs in 2010, 2009, and 2008, of which $3.9 million, $3.6 million, and $6.3 million, respectively, were included in accounts receivable as of December 31, 2010, 2009, and 2008. In addition, the up-front payments from sanofi-aventis of $80.0 million in September 2003 and $25.0 million in January 2006 were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2010, 2009, and 2008, we recognized $9.9 million, $9.9 million, and $8.8 million of revenue, respectively, related to these up-front payments.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of aflibercept development expenses will terminate and we will retain all rights to aflibercept.

Antibodies

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. In connection with the execution of the discovery agreement in 2007, we received a non-refundable up-front payment of $85.0 million from sanofi-aventis. Pursuant to the collaboration, sanofi-aventis is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $175 million of research from the collaboration's inception through December 31, 2009. In November 2009, we and sanofi-aventis amended these collaboration agreements to expand and extend our antibody collaboration. Under the amended discovery agreement, sanofi-aventis agreed to fund up to $160 million per year of our antibody discovery activities in 2010 through 2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3710

Samsung Bioepis Exhibit 1017, pg. 3710

were not satisfied. In 2010, as we scaled up our capacity to conduct antibody discovery activities, sanofi-aventis funded $137.7 million of our preclinical research under the amended discovery agreement. The balance between that amount and $160 million, or $22.3 million, has been added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement. The amended discovery agreement will expire on December 31, 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified through discovery research under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate (called Shared Phase 3 Trial Costs) are shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of $341.0 million as of December 31, 2010) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the license agreement, we retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured. In connection with the November 2009 amendment of the collaboration's discovery agreement, sanofi-aventis is funding up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $21.6 million had been received, and $1.8 million was included in accounts receivable, at December 31, 2010.

In 2010, 2009, and 2008, sanofi-aventis funded $137.7 million, $99.8 million, and $72.2 million, respectively, of our expenses under the collaboration's discovery agreement and $138.3 million, $98.3 million, and $25.7 million, respectively, of our development costs under the license agreement. Of these amounts, $73.4 million, $57.9 million and $25.5 million were included in accounts receivable as of December 31, 2010, 2009, and 2008, respectively. The $85.0 million up-front payment received from sanofi-aventis in December 2007 was recorded to deferred revenue and is being recognized as collaboration revenue over the period during which we expect to perform services. In addition, reimbursements by sanofi-aventis of our costs to expand our manufacturing capacity are recorded to deferred revenue and recognized prospectively as collaboration revenue over the same period applicable to recognition of the $85.0 million up-front payment. In 2010, 2009, and 2008, we recognized $7.3 million, $9.9 million, and $10.5 million of revenue, respectively, related to these deferred payments.

In connection with the antibody collaboration, in August 2008, we entered into a separate agreement with sanofi-aventis to use our proprietary *VelociGene*® technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. The agreement provides for minimum annual order quantities for the term of the agreement, which extends through December 2012, for which we expect to receive payments totaling a minimum of $21.5 million, of which $9.2 million had been received as of December 31, 2010.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3711

Samsung Bioepis Exhibit 1017, pg. 3711

aventis within thirty days of the date that sanofi-aventis elects to jointly develop such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party. Prior to December 31, 2017, sanofi-aventis has the right to terminate the amended discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2017. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

In December 2007, we sold sanofi-aventis 12 million newly issued, unregistered shares of Common Stock at an aggregate cash price of $312.0 million, or $26.00 per share of Common Stock. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with us. This agreement, which was amended in November 2009, contains certain demand rights, "stand-still provisions", and other restrictions, which are more fully described in Note 12 to our Financial Statements. In addition, in October 2010, sanofi-aventis purchased 1,017,401 shares of Common Stock in our underwritten public offering.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, VEGF Trap-Eye. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of $75.0 million. In August 2007, we received a $20.0 million milestone payment (which, for the purpose of revenue recognition, was not considered substantive) from Bayer HealthCare following dosing of the first patient in the VIEW 1 study of VEGF Trap-Eye in wet AMD. In July 2009, we received a $20.0 million substantive performance milestone payment from Bayer HealthCare following dosing of the first patient in the COPERNICUS study of VEGF Trap-Eye in CRVO. In both December 2010 and January 2011, we received a $10.0 million substantive milestone payment (for a total of $20.0 million) from Bayer HealthCare for achieving positive 52-week results in the VIEW 1 study and positive 6-month results in the COPERNICUS study, respectively. We are eligible to receive up to $50 million in future milestone payments related to marketing approvals of the VEGF Trap-Eye in major market countries outside the United States. We are also eligible to receive up to $135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of $241.2 million at December 31, 2010) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. Within the United States, we are responsible for any future commercialization of VEGF Trap-Eye and retain exclusive rights to any future profits from such commercialization in the United States. To date, we and Bayer HealthCare have initiated Phase 3 programs of VEGF Trap-Eye in wet AMD, CRVO, and CNV of the retina as a result of pathologic myopia, and a Phase 2 clinical study in DME. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

The $75.0 million up-front payment and the $20.0 million milestone payment received in August 2007 from Bayer HealthCare were recorded to deferred revenue. In 2010, 2009, and 2008, we recognized $9.9 million, $9.9 million, and $12.4 million, respectively, of revenue related to these payments. The $10.0 million substantive milestone payments received from Bayer HealthCare in each of December 2010 and January 2011 were recognized as collaboration revenue in 2010, and the $20.0 million substantive performance milestone payment received from Bayer HealthCare in July 2009 was recognized as collaboration revenue in 2009.

Under the terms of the agreement, in 2009 and thereafter, all agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared equally. In 2010 and 2009, this resulted in net payments by us of $2.6 million and $0.3 million, respectively, to Bayer HealthCare. In 2008, the first $70.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next $30.0 million, which resulted in a net payment by us of $11.3 million to Bayer HealthCare. At December 31, 2010 and 2009, accrued expenses included $2.3 million and $1.2 million, respectively, due to Bayer HealthCare.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3712

Samsung Bioepis Exhibit 1017, pg. 3712

Bayer HealthCare has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to VEGF Trap-Eye.

License Agreement with AstraZeneca

Under this non-exclusive license agreement, AstraZeneca made a $20.0 million annual, non-refundable payment to us in each of 2010, 2009, 2008, and 2007. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement, effective in February 2011. We remain entitled to receive mid-single digit royalties on any future sales of antibody products discovered by MedImmune using our *VelocImmune®* technology.

License Agreement with Astellas

Under this non-exclusive license agreement, Astellas made a $20.0 million annual, non-refundable payment to us in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010. In addition, Astellas will make a $130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune®* technology.

National Institutes of Health Grant

Under our five-year grant from the NIH, as amended, we are entitled to receive a minimum of $25.3 million over the five-year period beginning in September 2006, subject to compliance with the grant's terms and annual funding approvals, including $1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2010, 2009, and 2008, we recognized $4.6 million, $5.5 million, and $4.9 million, respectively, of revenue related to the NIH Grant, of which $1.0 million and $1.2 million, respectively, was receivable at the end of 2010 and 2009. Under the NIH grant, as amended, we have received $21.6 million from the grant's inception through December 31, 2010. In 2011, we expect to receive funding of approximately $3.7 million for reimbursement of our expenses related to the NIH Grant.

License Agreement with Cellectis

In July 2008, we and Cellectis S.A. entered into an Amended and Restated Non-Exclusive License Agreement. The amended license agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to the amended license agreement, in July 2008, we made a non-refundable $12.5 million payment to Cellectis and agreed to pay Cellectis a low single-digit royalty based on revenue received by us from any future licenses or sales of our *VelociGene®* or *VelocImmune® products and services.* No royalties are payable to Cellectis with respect to our *VelocImmune®* license agreements with AstraZeneca and Astellas or our antibody collaboration with sanofi-aventis. In addition, no royalties are payable to Cellectis on any revenue from commercial sales of antibodies from our *VelocImmune®* technology.

We are amortizing our $12.5 million payment to Cellectis in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis (as amended in November 2009). In 2010, 2009, and 2008 we recognized $0.9 million, $2.3 million, and $2.7 million, respectively, of expense related to the Cellectis agreement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3713

Samsung Bioepis Exhibit 1017, pg. 3713

Lease – Tarrytown, New York Facilities:

We lease approximately 545,600 square feet of laboratory and office space at facilities in Tarrytown, New York, under a December 2006 lease agreement, as amended. These facilities include approximately 230,000 square feet of newly constructed space in two new buildings (Buildings A and B) that were completed during the third quarter of 2009 and, under a December 2009 amendment to the lease, approximately 131,000 square feet of additional new space in a third new building (Building C), which we expect to occupy in early 2011. The lease will expire in June 2024 and contains three renewal options to extend the term of the lease by five years each, as well as early termination options on approximately 316,000 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Certain premises under the lease are accounted for as operating leases. However, for Buildings A, B, and C that we are leasing, we are deemed, in substance, to be the owner of the landlord's buildings in accordance with the application of FASB authoritative guidance, and the landlord's costs of constructing these new facilities are required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet.

In connection with the lease, we issued a letter of credit to our landlord, currently in the amount of $3.4 million, which is fully collateralized by cash and marketable securities.

In connection with Buildings A and B, we capitalized our landlord's costs of constructing these new facilities, which totaled $58.4 million as of December 31, 2010, and recognized a corresponding facility lease obligation of $58.4 million. We also recognized, as an additional facility lease obligation, reimbursements totaling $56.9 million from our landlord during 2010 and 2009 for tenant improvement costs that we incurred since, under FASB authoritative guidance, these reimbursements from our landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. At December 31, 2010 and 2009, the facility lease obligation balance in connection with Buildings A and B was $113.7 million and $81.0 million, respectively.

In addition, as described above, we amended our lease in December 2009 to include additional new laboratory and office space in Building C. As of December 31, 2010, we capitalized $27.8 million of our landlord's costs of constructing Building C and recognized a corresponding facility lease obligation of $27.8 million. We also recognized, as an additional facility lease obligation, reimbursements totaling $14.2 million from our landlord during 2010 for tenant improvement costs that we will incur since, under FASB authoritative guidance, these reimbursements from our landlord are deemed to be a financing obligation. Monthly lease payments on the Building C facilities commenced in January 2011 and additional charges for utilities, taxes, and operating expenses commenced in January 2010. Rent expense in connection with the land element of these additional facilities, which is accounted for as an operating lease, commenced in December 2010 and were recorded as a deferred liability until lease payments commence in January 2011. In addition, interest expense is imputed at a rate of approximately 9%, and is capitalized and deferred in connection with this facility lease obligation. At December 31, 2010 and 2009, the facility lease obligation balance in connection with Building C was $46.4 million and $28.0 million, respectively.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $99.7 million in 2010, $97.3 million in 2009, and $34.9 million in 2008. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, as described above, sanofi-aventis has funded $22.9 million of agreed-upon capital expenditures incurred by us during 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at December 31, 2010.

We expect to incur capital expenditures of approximately $50 to $75 million in 2011, primarily in connection with tenant improvements at our leased Tarrytown facilities, capital improvements at our Rensselaer, New York manufacturing facilities, and purchases of equipment. We expect to be reimbursed for a portion of these capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3714

Samsung Bioepis Exhibit 1017, pg. 3714

Funding Requirements

Our total expenses for research and development from inception through December 31, 2010 were approximately $2.5 billion. We have entered into various agreements related to our activities to develop and commercialize product candidates and utilize our technology platforms, including collaboration agreements such as those with sanofi-aventis and Bayer HealthCare, and agreements to use our *Velocigene*® technology platform. We incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost sharing of collaborator's development expenses, where applicable, of $431.4 million, $333.7 million, and $230.6 million in 2010, 2009, and 2008, respectively.

We expect to continue to incur substantial funding requirements for research and development activities (including preclinical and clinical testing). As described above, expenses that we incur in connection with our aflibercept and antibodies collaborations are, generally, fully funded by sanofi-aventis. In addition, as described above, we and Bayer HealthCare share agreed-upon development expenses that both companies incur in connection with our VEGF Trap-Eye collaboration. After taking into account anticipated reimbursements from our collaborators, we currently estimate that approximately 30-40% of our funding requirements for 2011 will be directed toward technology development, basic research and early preclinical activities, and the preclinical and clinical development of our product candidates (principally, for ARCALYST® and VEGF Trap-Eye). For 2011, we also currently estimate that approximately 20-30% of our funding requirements will be directed toward preparing for the potential commercialization of our late-stage product candidates; approximately 15-25% of our funding requirements will be applied to capital expenditures (as described above); and the remainder of our funding requirements will be used for general corporate purposes.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2010. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

		Payments Due by Period			
	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
			(In millions)		
Operating leases[1]	$ 96.3	$ 6.3	$12.2	$13.6	$ 64.2
Capital leases	3.2	1.1	2.1		
Purchase obligations[2]	108.6	99.2	9.4		
Other long-term liabilities[3]	250.0	13.8	32.5	35.4	168.3
Total contractual obligations	$458.1	$120.4	$56.2	$49.0	$232.5

(1) Excludes future contingent costs for utilities, real estate taxes, and operating expenses. In 2010, these costs were $10.3 million. See Note 11(a) to our Financial Statements.

(2) Purchase obligations primarily relate to (i) research and development commitments, including those related to clinical trials, (ii) capital expenditures for equipment acquisitions, and (iii) license payments. Our obligation to pay certain of these amounts may increase or be reduced based on certain future events. Open purchase orders for the acquisition of goods and services in the ordinary course of business are excluded from the table above.

(3) Represents payments with respect to facility lease obligations in connection with our lease of facilities in Tarrytown, New York, as described above. See Note 11 (a) to our Financial Statements.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare will share agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as described above. In addition, under our collaboration agreements with sanofi-aventis and Bayer HealthCare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by sanofi-aventis and Bayer HealthCare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for our aflibercept collaboration with sanofi-aventis, royalties on product sales in Japan) otherwise payable to us, unless, in some cases, we elect to reimburse these expenses at a faster rate. Given the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3715

Samsung Bioepis Exhibit 1017, pg. 3715

uncertainties related to drug development (including the development of aflibercept and co-developed antibody candidates in collaboration with sanofi-aventis and VEGF Trap-Eye in collaboration with Bayer HealthCare), such as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer HealthCare will become profitable.

The amount we need to fund operations will depend on various factors, including the potential regulatory approval and commercialization of our product candidates, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and pending or future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Our commercialization costs over approximately the next few years will depend on, among other things, the results of Phase 3 clinical trials of our late-stage product candidates and whether and when such product candidates receive regulatory approval, market potential for such product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or share the profits from such sales pursuant to our license or collaboration agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, in connection with preparing to commercialize and launch potential products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we anticipate that we would (i) seek sources of additional capital through collaborative arrangements and/or additional public or private financing, including debt and equity financing and/or (ii) prioritize available capital to fund selected preclinical and clinical development programs and/or preparations for the potential commercialization of our late-stage product candidates, or license selected products.

Other than letters of credits totaling $3.8 million, including the $3.4 million letter of credit issued in connection with our lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of December 31, 2010, we had $0.7 million of financing available under a capital equipment lease line. Aside from this lease line, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3716

Samsung Bioepis Exhibit 1017, pg. 3716

Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate consideration to be received in a multiple-element revenue arrangement by requiring the use of estimated selling prices to allocate the consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We will adopt this amended guidance effective for the fiscal year beginning January 1, 2011. We do not anticipate that the adoption of this guidance will have a material impact on our financial statements.

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We will adopt this amended guidance for the fiscal year beginning January 1, 2011. We do not anticipate that the adoption of this guidance will have a material impact on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $5.9 million and $0.6 million decrease in the fair value of our investment portfolio at December 31, 2010 and 2009, respectively. The increase in interest rate risk year over year is due primarily to higher balances of marketable debt securities with maturities in excess of one year that we held at December 31, 2010 compared to 2009.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of $0.1 million, $0.1 million, and $2.5 million in 2010, 2009, and 2008, respectively.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included on pages F-1 through F-34 of this report. The supplementary financial information required by this Item is included at page F-34 of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3717

Samsung Bioepis Exhibit 1017, pg. 3717

the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2010. The effectiveness of our internal control over financial reporting as of December 31, 2010 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

ITEM 9B. OTHER INFORMATION

None.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3718

Samsung Bioepis Exhibit 1017, pg. 3718

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our officers, directors, and employees. The full text of our code of business conduct and ethics can be found on the Company's website (http://www.regeneron.com) under the "Corporate Governance" heading on the "About Us" page. We may satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or a waiver from, a provision of our code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions, by posting such information on our website where it is accessible through the same link noted above.

ITEM 11. EXECUTIVE COMPENSATION

The information called for by this item will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and, therefore, have been omitted.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3719

Samsung Bioepis Exhibit 1017, pg. 3719

3. Exhibits

Exhibit Number			Description
3.1	(m)	-	Restated Certificate of Incorporation.
3.2	(a)	-	By-Laws, as amended.
10.1 +	(o)	-	Amended and Restated 2000 Long-Term Incentive Plan.
10.1.1 +	(b)	-	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10.1.2 +	(b)	-	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.1.3 +	(c)	-	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.1.4 +	(c)	-	Form of option agreement and related notice of grant for use in connection with the grant of stock options to certain of the Registrant's executive officers in connection with a January 2005 Option Exchange Program.
10.1.5 +	(s)	-	Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors and executive officers.
10.1.6 +	(s)	-	Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the Registrant's executive officers.
10.1.7 +		-	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers (revised).
10.1.8 +		-	Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the Registrant's executive officers (revised).
10.2 +	(r)	-	Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D.
10.3* +	(d)	-	Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D.
10.4 +	(r)	-	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008.
10.5*	(e)	-	IL-1 License Agreement, dated June 26, 2002, by and among the Registrant, Immunex Corporation, and Amgen Inc.
10.6*	(t)	-	IL-1 Antibody Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.
10.7*	(t)	-	Trap-2 Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.
10.8*	(f)	-	Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.8.1*	(d)	-	Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 31, 2004.
10.8.2	(g)	-	Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of January 7, 2005.
10.8.3*	(h)	-	Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 21, 2005.
10.8.4*	(h)	-	Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals, Inc.) and the Registrant, effective as of January 31, 2006.
10.9*	(i)	-	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and the Registrant.
10.10*	(j)	-	Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007, by and between AstraZeneca UK Limited and the Registrant.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3720

Samsung Bioepis Exhibit 1017, pg. 3720

10.11	(k)	-	Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and the Registrant.
10.11.1*	(m)	-	First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of October 24, 2007.
10.11.2	(q)	-	Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of September 30, 2008.
10.11.3	(s)	-	Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 29, 2009.
10.11.4	(u)	-	Fourth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of December 3, 2009.
10.11.5	(v)	-	Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010.
10.11.6	(x)	-	Sixth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 4, 2010.
10.11.7		-	Seventh Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of December 22, 2010.
10.12*	(l)	-	Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and the Registrant.
10.12.1*	(y)	-	Amendment to the Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007 by and between Astellas Pharma Inc. and the Registrant, dated as of July 28, 2010.
10.13*	(w)	-	Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.14*	(w)	-	Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique Du Nord, and the Registrant.
10.15	(n)	-	Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique Du Nord, sanofi-aventis US LLC, and the Registrant.
10.16	(n)	-	Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and the Registrant.
10.16.1	(w)	-	First Amendment to the December 20, 2007 Investor Agreement, dated as of November 10, 2009, by and among sanofi-aventis US LLC, Aventis Pharmaceuticals, Inc., sanofi-aventis Amerique du Nord, and the Registrant.
10.17*	(p)	-	Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Cellectis, S.A. and the Registrant.
23.1		-	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1		-	Power of Attorney (included on the signature page of this Annual Report on Form 10-K).
31.1		-	Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2		-	Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32		-	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101		-	Interactive Data File
101.INS		-	XBRL Instance Document
101.SCH		-	XBRL Taxonomy Extension Schema
101.CAL		-	XBRL Taxonomy Extension Calculation Linkbase
101.LAB		-	XBRL Taxonomy Extension Label Linkbase
101.PRE		-	XBRL Taxonomy Extension Presentation Linkbase
101.DEF		-	XBRL Taxonomy Extension Definition Document

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3721

Samsung Bioepis Exhibit 1017, pg. 3721

(a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.

(b) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.

(c) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.

(d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2004, filed March 11, 2005.

(e) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2002, filed August 13, 2002.

(f) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2003, filed November 12, 2003.

(g) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.

(h) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2005, filed February 28, 2006.

(i) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.

(j) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2006, filed March 12, 2007.

(k) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.

(l) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2007, filed May 4, 2007.

(m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2007, filed November 7, 2007.

(n) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2007, filed February 27, 2008.

(o) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed June 17, 2008.

(p) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2008, filed August 1, 2008.

(q) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2008, filed November 5, 2008.

(r) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2008, filed February 26, 2009.

(s) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2009, filed April 30, 2009.

(t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2009, filed August 4, 2009.

(u) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 8, 2009.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3722

Samsung Bioepis Exhibit 1017, pg. 3722

(v) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed February 16, 2010.

(w) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2009, filed February 18, 2010.

(x) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2010, filed July 28, 2010.

(y) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2010, filed October 28, 2010.

---

* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

\+ Indicates a management contract or compensatory plan or arrangement.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3723

Samsung Bioepis Exhibit 1017, pg. 3723

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

By: /s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Dated: Tarrytown, New York
February 17, 2011

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Murray A. Goldberg, Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, and each of them, his true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	*Title*
/s/ LEONARD S. SCHLEIFER, Leonard S. Schleifer, M.D., Ph.D.	*President, Chief Executive Officer, and Director (Principal Executive Officer)*
/s/ MURRAY A. GOLDBERG Murray A. Goldberg	*Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer)*
/s/ DOUGLAS S. MCCORKLE Douglas S. McCorkle	*Vice President, Controller, and Assistant Treasurer (Principal Accounting Officer)*
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D	*Executive Vice President, Chief Scientific Officer, President, Regeneron Research Laboratories, and Director*
/s/ P. ROY VAGELOS P. Roy Vagelos, M.D.	*Chairman of the Board*
/s/ CHARLES A. BAKER Charles A. Baker	*Director*
/s/ MICHAEL S. BROWN Michael S. Brown, M.D.	*Director*
/s/ ALFRED G. GILMAN Alfred G. Gilman, M.D., Ph.D.	*Director*
/s/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	*Director*
/s/ CHRISTINE A. POON Christine A. Poon	*Director*
/s/ ARTHUR F. RYAN Arthur F. Ryan	*Director*

/s/ ERIC M. SHOOTER — *Director*

Eric M. Shooter, Ph.D.

/s/ GEORGE L. SING — *Director*

George L. Sing

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3725

Samsung Bioepis Exhibit 1017, pg. 3725

REGENERON PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.	Page Numbers
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets at December 31, 2010 and 2009	F-3
Statements of Operations for the years ended December 31, 2010, 2009, and 2008	F-4
Statements of Stockholders' Equity for the years ended December 31, 2010, 2009, and 2008	F-5
Statements of Cash Flows for the years ended December 31, 2010, 2009, and 2008	F-6
Notes to Financial Statements	F-7 to F-34

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3726

Samsung Bioepis Exhibit 1017, pg. 3726

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Regeneron Pharmaceuticals, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. at December 31, 2010 and December 31, 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

New York, New York
February 17, 2011

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3727

Samsung Bioepis Exhibit 1017, pg. 3727

REGENERON PHARMACEUTICALS, INC.
BALANCE SHEETS

December 31, 2010 and 2009
(In thousands, except share data)

	2010	2009
ASSETS		
Current assets		
Cash and cash equivalents	$ 112,572	$ 207,075
Marketable securities	136,796	134,255
Accounts receivable from the sanofi-aventis Group	79,603	62,703
Accounts receivable - other	13,509	2,865
Prepaid expenses and other current assets	15,142	18,610
Total current assets	357,622	425,508
Restricted cash and marketable securities	7,518	1,600
Marketable securities	370,053	47,080
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	347,450	259,676
Other assets	6,789	7,338
Total assets	$ 1,089,432	$ 741,202
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 53,658	$ 49,031
Deferred revenue from sanofi-aventis, current portion	19,306	17,523
Deferred revenue - other, current portion	35,217	27,021
Facility lease obligations, current portion	675	
Total current liabilities	109,056	93,575
Deferred revenue from sanofi-aventis	97,081	90,933
Deferred revenue - other	188,775	46,951
Facility lease obligations	139,355	109,022
Other long term liabilities	7,350	3,959
Total liabilities	561,617	344,440
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value: 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, $.001 par value: 40,000,000 shares authorized; shares issued and outstanding - 2,182,036 in 2010 and 2,244,698 in 2009	2	2
Common Stock, $.001 par value: 160,000,000 shares authorized; shares issued and outstanding - 87,238,301 in 2010 and 78,860,862 in 2009	87	79
Additional paid-in capital	1,575,780	1,336,732
Accumulated deficit	(1,043,563)	(941,095)
Accumulated other comprehensive (loss) income	(2,491)	1,044
Total stockholders' equity	527,815	396,762
Total liabilities and stockholders' equity	$ 1,089,432	$ 741,202

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3728

Samsung Bioepis Exhibit 1017, pg. 3728

REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2010, 2009, and 2008
(In thousands except share data)

	2010	2009	2008
Revenues			
Sanofi-aventis collaboration revenue	$ 311,332	$247,140	$153,972
Other collaboration revenue	75,393	67,317	31,166
Technology licensing	40,150	40,013	40,000
Net product sales	25,254	18,364	6,249
Contract research and other	6,945	6,434	7,070
	459,074	379,268	238,457
Expenses			
Research and development	489,252	398,762	274,903
Selling, general, and administrative	65,201	52,923	48,880
Cost of goods sold	2,093	1,686	923
	556,546	453,371	324,706
Loss from operations	(97,472)	(74,103)	(86,249)
Other income (expense)			
Investment income	2,122	4,488	18,161
Interest expense	(9,118)	(2,337)	(7,752)
Loss on early extinguishment of debt			(938)
	(6,996)	2,151	9,471
Net loss before income tax expense	(104,468)	(71,952)	(76,778)
Income tax (benefit) expense		(4,122)	2,351
Net loss	$(104,468)	$ (67,830)	$ (79,129)
Net loss per share, basic and diluted	$ (1.26)	$ (0.85)	$ (1.00)
Weighted average shares outstanding, basic and diluted	82,926	79,782	78,827

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3729

Samsung Bioepis Exhibit 1017, pg. 3729

REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2010, 2009, and 2008
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2007	2,260	$2	76,592	577	$1,253,235	$ (794,136)	$ 170	$ 459,848	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			980	1	7,948			7,949	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			59		1,107			1,107	
Conversion of Class A Stock to Common Stock	(11)		11						
Stock-based compensation expense					12,523			12,523	
Net loss, 2008						(79,129)		(79,129)	$ (79,129)
Change in net unrealized gain (loss) on marketable securities							(284)	(284)	(284)
Balance, December 31, 2008	2,249	2	77,642	78	1,294,813	(873,265)	(114)	421,514	$ (79,413)
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			1,134	1	9,269			9,270	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			81		1,391			1,391	
Conversion of Class A Stock to Common Stock	(4)		4						
Stock-based compensation expense					31,259			31,259	
Net loss, 2009						(67,830)		(67,830)	$ (67,830)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.7 million							1,158	1,158	1,158
Balance, December 31, 2009	2,245	2	78,861	79	1,336,732	(941,095)	1,044	396,762	$ (66,672)
Issuance of Common Stock in a public offering, net of issuance costs			6,325	6	174,822			174,828	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			1,533	1	21,463			21,464	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			111		2,867			2,867	
Issuance of restricted Common Stock under Long-Term Incentive Plan			345						
Conversion of Class A Stock to Common Stock	(63)		63						
Stock-based compensation expense					19,897			19,897	
Net loss, 2010						(104,468)		(104,468)	$(104,468)
Change in net unrealized gain (loss) on marketable securities							(3,535)	(3,535)	(3,535)
Balance, December 31, 2010	2,182	$2	87,238	$87	$1,575,780	$(1,045,563)	$(2,491)	$ 527,815	$(108,003)

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3730

Samsung Bioepis Exhibit 1017, pg. 3730

REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2010, 2009, and 2008
(In thousands)

	2010	2009	2008
Cash flows from operating activities			
Net loss	$(104,468)	$ (67,830)	$ (79,129)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities			
Depreciation and amortization	19,687	14,247	11,287
Non-cash compensation expense	39,897	31,259	32,523
Loss on early extinguishment of debt			938
Net realized loss (gain) on marketable securities	293	(56)	1,310
Changes in assets and liabilities			
Increase in accounts receivable	(27,544)	(30,356)	(16,892)
Decrease (increase) in prepaid expenses and other assets	2,723	(4,574)	(6,560)
Increase (decrease) in deferred revenue	158,151	(27,497)	(26,834)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	7,605	12,577	(5,729)
Total adjustments	200,812	(4,400)	(9,957)
Net cash provided by (used in) operating activities	96,344	(72,230)	(89,086)
Cash flows from investing activities			
Purchases of marketable securities	(605,124)	(199,997)	(581,139)
Sales or maturities of marketable securities	276,601	297,411	646,861
Purchases of restricted marketable securities	(7,063)		
Decrease (increase) in restricted cash	1,122	50	(50)
Capital expenditures	(99,689)	(97,318)	(34,857)
Net cash (used in) provided by investing activities	(434,153)	146	30,815
Cash flows from financing activities			
Repurchases or repayment of notes payable			(200,807)
Proceeds in connection with facility lease obligation	47,544	23,640	
Payments in connection with facility lease obligation	(924)	(875)	
Net proceeds from the issuance of Common Stock	196,790	8,598	7,949
Payments in connection with capital lease obligation	(104)		
Net cash provided by (used in) financing activities	243,306	31,363	(192,858)
Net decrease in cash and cash equivalents	(94,503)	(40,721)	(251,129)
Cash and cash equivalents at beginning of period	207,075	247,796	498,925
Cash and cash equivalents at end of period	$ 112,572	$ 207,075	$ 247,796
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 12,737	$ 2,525	$ 9,348
Cash paid for income taxes			$ 3,079

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3731

Samsung Bioepis Exhibit 1017, pg. 3731

1. Organization and Business

Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") was incorporated in January 1988 in the State of New York. The Company is engaged in the research, development, and commercialization of pharmaceutical products for the treatment of serious medical conditions. In 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for the Company's first commercial drug product, ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company's facilities are primarily located in New York. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, obtaining regulatory approvals, commercializing products, and obtaining and enforcing patents.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

For purposes of the statement of cash flows and the balance sheet, the Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

Marketable Securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company has invested its excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. The Company considers its marketable securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board ("FASB"). These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in the Company's investment portfolio is deemed to be other-than-temporary, the Company writes down the security to its current fair value and recognizes a loss that may be charged against income. As described under "Use of Estimates" below, on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary.

Inventory

Inventories are stated at the lower of cost or estimated realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method. The Company capitalizes inventory costs associated with the Company's products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate.

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	10-40 years
Laboratory and other equipment	3-10 years
Furniture and fixtures	5 years

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3732

Samsung Bioepis Exhibit 1017, pg. 3732

Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the lease term, without assuming renewal features, if any, are exercised. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

Accounting for the Impairment of Long-Lived Assets

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount. For all periods presented, no impairment losses were recorded.

Patents

As a result of the Company's research and development efforts, the Company obtains and applies for patents to protect proprietary technology and inventions. All costs associated with patents for product candidates under development are expensed as incurred. Patent costs related to commercial products are capitalized and amortized over the shorter of their estimated useful life or the remaining patent term. To date, the Company has no capitalized patent costs.

Operating Leases

On certain of its operating lease agreements, the Company may receive rent holidays and other incentives. The Company recognizes operating lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays that defer the commencement date of required payments. In addition, lease incentives that the Company receives are treated as a reduction of rent expense over the term of the related agreements.

Revenue Recognition

a. Collaboration Revenue

The Company earns collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize the Company's technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, such as in the Company's VEGF Trap-Eye collaboration with Bayer HealthCare LLC, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities, such as in the Company's aflibercept and antibody collaborations with the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3733

Samsung Bioepis Exhibit 1017, pg. 3733

sanofi-aventis Group. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as collaboration revenue proportionately as the Company recognizes its expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, in periods when the Company's collaborator incurs development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of the collaborator's development expenses that the Company is obligated to reimburse.

In connection with non-refundable licensing payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, estimated performance periods may change if development programs encounter delays, or the Company and its collaborators decide to expand or contract the clinical plans for a drug candidate in various disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, the Company would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

b. *VelocImmune*® Technology Licensing

The Company enters into non-exclusive license agreements with third parties that allow the third party to utilize the Company's *VelocImmune*® technology in its internal research programs. The terms of these agreements include up-front payments and entitle the Company to receive royalties on any future sales of products discovered by the third party using the Company's *VelocImmune*® technology. Up-front payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective license periods.

c. Product Revenue

Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and the Company has no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distribution fees, and other sales-related deductions. The Company reviews its estimates of rebates payable each period and records any necessary adjustments in the current period's net product sales.

Investment Income

Interest income, which is included in investment income, is recognized as earned.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements, the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3734

Samsung Bioepis Exhibit 1017, pg. 3734

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations ("CROs"), independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and/or the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by CROs. CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of the Company's contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues expense on an estimated cost-per-patient basis, based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates. The Company's estimates and assumptions for clinical expense recognition could differ significantly from its actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

Stock-based Compensation

The Company recognizes stock-based compensation expense for grants of stock option awards and restricted stock under the Company's Long-Term Incentive Plans, to employees and non-employee members of the Company's board of directors, based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. In addition, the Company has granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, the Company estimates that these options will vest, which is based on whether the Company consider the options' performance conditions to be probable of attainment. The Company's estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods.

The Company uses the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of the board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Common Stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3735

Samsung Bioepis Exhibit 1017, pg. 3735

Income Taxes

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain.

Uncertain tax positions are accounted for in accordance with FASB authoritative guidance, which prescribes a comprehensive model for the manner in which a company should recognize, measure, present, and disclose in its financial statements all material uncertain tax positions that the company has taken or expects to take on a tax return. Those positions, for which management's assessment is that there is more than a 50% probability of sustaining the position upon challenge by a taxing authority based upon its technical merits, are subjected to certain measurement criteria.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense.

Comprehensive Income (Loss)

Comprehensive income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities, net of any tax effect. Comprehensive income (loss) for the years ended December 31, 2010, 2009, and 2008 have been included in the Statements of Stockholders' Equity.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities (see Note 6), and receivables from sanofi-aventis.

Per Share Data

Net income (loss) per share, basic and diluted, is computed on the basis of the net income (loss) for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock outstanding, and of common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the "treasury stock method" when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's formerly outstanding convertible senior subordinated notes, which are included under the "if-converted method" when dilutive. The computation of diluted net loss per share for the years ended December 31, 2010, 2009, and 2008 does not include common stock equivalents, since such inclusion would be antidilutive.

Risks and Uncertainties

Developing and commercializing new medicines entails significant risk and expense. Since its inception, the Company has not generated any significant sales or profits from the commercialization of ARCALYST® or any of the Company's other product candidates. Before revenues from the commercialization of the Company's current or future product candidates can be realized, the Company (or its collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render the Company's products and technologies uncompetitive or obsolete. The Company may be subject to legal claims by third parties seeking to enforce patents to limit or prohibit the Company from marketing or selling its products. The Company is also dependent upon the services

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3736

Samsung Bioepis Exhibit 1017, pg. 3736

of its employees, consultants, collaborators, and certain third-party suppliers, including single-source unaffiliated third-party suppliers of certain raw materials and equipment. Regeneron, as licensee, licenses certain technologies that are important to the Company's business which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate the Company's licenses.

The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) up-front, license, milestone, and reimbursement payments from the Company's collaborators and other entities related to the Company's development activities and technology platforms, (ii) payments for past contract manufacturing activities, (iii) ARCALYST® product sales, and (iv) investment income. Collaboration revenue in 2010 was earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 3 for the terms of these agreements). These collaboration agreements contain early termination provisions that are exercisable by sanofi-aventis or Bayer HealthCare, as applicable.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Estimates which could have a significant impact on the Company's financial statements include:

- Product rebates and returns in connection with the recognition of revenue from product sales.
- Periods over which payments, including non-refundable up-front, license, and milestone payments, are recognized as revenue in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms.
- Periods over which certain clinical trial costs, including costs for clinical activities performed by contract research organizations, are recognized as research and development expenses.
- In connection with stock option awards, (i) the fair value of stock options on their date of grant using the Black-Scholes option-pricing model, based on assumptions with respect to (a) expected volatility of the Company's Common Stock price, (b) the periods of time for which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (c) expected dividend yield on the Company's Common Stock, and (d) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives; (ii) the number of stock option awards that are expected to be forfeited; and (iii) with respect to performance-based stock option awards, if and when the options' performance conditions are considered to be probable of attainment.
- The Company's determination of whether marketable securities are other than temporarily impaired. The Company conducts a quarterly review of its portfolio of marketable securities, using both quantitative and qualitative factors, to determine, for securities whose current fair value is less than their cost, whether the decline in fair value below cost is other-than-temporary. In making this determination, the Company considers factors such as the length of time and the extent to which fair value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of the Company's ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.
- Useful lives of property, plant, and equipment.
- Capitalized inventory costs associated with the Company's products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized.
- The extent to which deferred tax assets and liabilities are offset by a valuation allowance.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3737

Samsung Bioepis Exhibit 1017, pg. 3737

In addition, the Company's share of VEGF Trap-Eye development expenses incurred by Bayer HealthCare, including the Company's share of Bayer HealthCare's estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter, are included in research and development expenses. The Bayer HealthCare estimate for the most recent fiscal quarter is adjusted in the subsequent quarter to reflect actual expenses for the quarter.

Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate consideration to be received in a multiple-element revenue arrangement by requiring the use of estimated selling prices to allocate the consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company will adopt this amended guidance effective for the fiscal year beginning January 1, 2011. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. The Company will adopt this amended guidance for the fiscal year beginning January 1, 2011. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

3. Collaboration and Contract Research Agreements

The Company has entered into various agreements related to its activities to develop and commercialize product candidates and utilize its technology platforms. Amounts earned by the Company in connection with these agreements totaled $393.7 million, $320.9 million, and $192.2 million in 2010, 2009, and 2008, respectively. Total Company-incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost-sharing of a collaborator's development expenses, where applicable (see Bayer HealthCare below), were $431.4 million, $333.7 million, and $230.6 million in 2010, 2009, and 2008, respectively. Significant agreements of this kind are described below.

a. The sanofi-aventis Group

Aflibercept

In September 2003, the Company entered into a collaboration agreement (the "Aflibercept Agreement") with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.), to jointly develop and commercialize aflibercept. In connection with this agreement, sanofi-aventis made a non-refundable up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for $45.0 million.

In January 2005, the Company and sanofi-aventis amended the Aflibercept Agreement to exclude intraocular delivery of aflibercept to the eye ("Intraocular Delivery") from joint development under the agreement, and product rights to aflibercept in Intraocular Delivery reverted to Regeneron. In connection with this amendment, sanofi-aventis made a $25.0 million non-refundable payment to Regeneron (the "Intraocular Termination Payment").

In December 2005, the Company and sanofi-aventis amended the Aflibercept Agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a $25.0 million non-refundable up-front payment to the Company, which was received in January 2006. Under the Aflibercept Agreement, as amended, the Company and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan, for disease indications included in the companies' collaboration. The Company is entitled to a royalty of approximately 35% on annual sales of aflibercept in Japan, subject to certain potential adjustments. The Company may also receive up to $400 million

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3738

Samsung Bioepis Exhibit 1017, pg. 3738

in milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

Under the Aflibercept Agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of these development expenses, or half of $707.3 million as of December 31, 2010, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits and Japan royalties, or at a faster rate at Regeneron's option. Regeneron has the option to conduct additional pre-Phase III studies at its own expense. In connection with the January 2005 amendment to the Aflibercept Agreement, the Intraocular Termination Payment of $25.0 million will be considered an aflibercept development expense and will be subject to 50% reimbursement by Regeneron to sanofi-aventis, as described above, if the collaboration becomes profitable. In addition, if the first commercial sale of an aflibercept product in Intraocular Delivery predates the first commercial sale of an aflibercept product under the collaboration by two years, Regeneron will begin reimbursing sanofi-aventis for up to $7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, Regeneron's obligation to reimburse sanofi-aventis, for 50% of aflibercept development expenses will terminate, and the Company will retain all rights to aflibercept.

In accordance with the Company's revenue recognition policy described in Note 2, the up-front payments received in September 2003 and January 2006, of $80.0 million and $25.0 million, respectively, and reimbursement of Regeneron-incurred development expenses, are being recognized as collaboration revenue over the related performance period. During the fourth quarter of 2008, the Company shortened its estimated performance period in connection with the $80.0 million and $25.0 million up-front payments from sanofi-aventis. The net effect of this change in the Company's estimate resulted in the recognition of an additional $1.2 million in collaboration revenue in 2010 and 2009, compared to amounts recognized in connection with these deferred payments in 2008.

The Company recognized $26.4 million, $36.5 million, and $44.4 million of collaboration development revenue in 2010, 2009, and 2008, respectively, in connection with the Aflibercept Agreement, as amended. At December 31, 2010 and 2009, amounts receivable from sanofi-aventis totaled $3.9 million and $3.6 million, respectively, and deferred revenue was $32.6 million and $42.5 million, respectively, in connection with the Aflibercept Agreement.

Antibodies

In November 2007, the Company entered into a global, strategic collaboration (the "Antibody Collaboration") with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. In connection with the collaboration, in December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for $312.0 million (see Note 12).

The Antibody Collaboration is governed by a Discovery and Preclinical Development Agreement (the "Discovery Agreement") and a License and Collaboration Agreement (the "License Agreement"). The Company received a non-refundable up-front payment of $85.0 million from sanofi-aventis under the Discovery Agreement. In addition, under the Discovery Agreement, sanofi-aventis is funding the Company's research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded $174.5 million of such research from the collaboration's inception through December 31, 2009. In November 2009, the Company and sanofi-aventis amended these collaboration agreements to expand and extend the Antibody Collaboration. Pursuant to the Discovery Agreement, as amended, sanofi-aventis agreed to fund up to $160 million per year of the Company's research activities in 2010 through 2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria were not satisfied. In 2010, as the Company scaled up its capacity to conduct

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3739

Samsung Bioepis Exhibit 1017, pg. 3739

antibody discovery activities, sanofi-aventis funded $137.7 million of the Company's preclinical research under the amended Discovery Agreement. The balance between that amount and $160 million, or $22.3 million, has been added to the funding otherwise available to the Company in 2011-2012 under the amended Discovery Agreement. The amended Discovery Agreement will expire on December 31, 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the Discovery Agreement, sanofi-aventis has the option to license rights to the candidate under the License Agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with the Company through product approval. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the License Agreement, the Company retains the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The Company and sanofi-aventis are currently co-developing eight therapeutic antibodies under the License Agreement.

Under the License Agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by sanofi-aventis and 20% by Regeneron. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of $341.0 million as of December 31, 2010) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products. However, the Company is not required to apply more than 10% of its share of the profits from the antibody collaboration in any calendar quarter to reimburse sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the License Agreement, subject to the Company's right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (Regeneron) and ending at 55% (sanofi-aventis)/45% (Regeneron), and losses outside the United States at 55% (sanofi-aventis)/45% (Regeneron). In addition to profit sharing, the Company is entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured. In connection with the November 2009 amendment of the collaboration's Discovery Agreement, sanofi-aventis is funding up to $30 million of agreed-upon costs incurred by the Company to expand its manufacturing capacity at the Company's Rensselaer, New York facilities, of which $23.4 million has been received or is receivable at December 31, 2010.

With respect to each antibody product which enters development under the License Agreement, sanofi-aventis or the Company may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. The Company may also opt-out of the further development of an antibody product if it gives notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the License Agreement. Each of the Discovery Agreement and the License Agreement contains other termination provisions, including for material breach by the other party. Prior to December 31, 2017, sanofi-aventis has the right to terminate the amended Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to the Company the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2017. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate. Upon expiration of the amended Discovery Agreement, sanofi-aventis has an option to license the Company's *VelocImmune*® technology for agreed upon consideration.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3740

Samsung Bioepis Exhibit 1017, pg. 3740

In connection with the Antibody Collaboration, in August 2008, the Company entered into a separate agreement with sanofi-aventis to use Regeneron's proprietary *VelociGene®* technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease (the "*VelociGene®* Agreement"). The *VelociGene®* Agreement provides for minimum annual order quantities for the term of the agreement, which extends through December 2012, for which the Company expects to receive payments totaling a minimum of $21.5 million.

In accordance with the Company's revenue recognition policy described in Note 2, the (i) $85.0 million up-front payment received in December 2007, (ii) reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements, (iii) $21.5 million of aggregate minimum payments under the *VelociGene®* Agreement, and (iv) reimbursement of agreed-upon costs to expand the Company's manufacturing capacity are being recognized as collaboration revenue over the related performance period. In connection with the amendments to expand and extend the Company's antibody collaboration with sanofi-aventis, during the fourth quarter of 2009, the Company extended its estimated performance period related to the $85.0 million up-front payment received from sanofi-aventis under the Discovery Agreement and the $21.5 million of aggregate minimum payments under the *VelociGene®* Agreement The effect of this change in estimate resulted in the recognition of $5.3 million less in collaboration revenue in 2010, compared to 2009.

In connection with the Antibody Collaboration, the Company recognized $284.9 million, $210.7 million, and $109.6 million of collaboration revenue in 2010, 2009, and 2008, respectively. In addition, at December 31, 2010 and 2009, amounts receivable from sanofi-aventis totaled $75.7 million and $59.1 million and deferred revenue was $84.0 million and $66.0 million, respectively.

b. Bayer HealthCare LLC

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to the Company of $75.0 million. In August 2007, the Company received a $20.0 million milestone payment from Bayer HealthCare (which, for the purpose of revenue recognition, was not considered substantive) following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in the neovascular form of age-related macular degeneration ("wet AMD"). In July 2009, the Company received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in Central Retinal Vein Occlusion ("CRVO"). In the fourth quarter of 2010, the Company earned two $10.0 million substantive milestone payments (for a total of $20.0 million) from Bayer HealthCare for achieving positive 52-week results in the Phase 3 study of VEGF Trap-Eye in wet AMD and positive 6-month results in the Phase 3 study of VEGF Trap-Eye in CRVO. One of these $10.0 million payments was received in December 2010 and the other $10.0 million payment was received in January 2011. The Company is eligible to receive up to $50 million in future milestone payments related to marketing approvals of VEGF Trap-Eye in major market countries outside the United States. The Company is also eligible to receive up to $135 million in sales milestone payments when and if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer HealthCare out of its share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of $241.2 million as of December 31, 2010) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. Within the United States, the Company is responsible for any future commercialization of VEGF Trap-Eye and retains exclusive rights to any future profits from such commercialization in the United States.

In 2008, the first $70.0 million of agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, were shared equally and the Company was solely responsible for up to the next $30.0 million of development expenses. In 2009 and thereafter, all development expenses are being shared equally. The Company is also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3741

Samsung Bioepis Exhibit 1017, pg. 3741

Bayer HealthCare has the right to terminate the Bayer Agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to VEGF Trap-Eye.

The $75.0 million up-front licensing payment and the $20.0 million milestone payment received in August 2007 from Bayer HealthCare are being recognized as collaboration revenue over the related estimated performance period in accordance with the Company's revenue recognition policy as described in Note 2. During the fourth quarter of 2008, the Company extended the estimated performance period in connection with these up-front and non-substantive milestone payments, which resulted in the recognition of $2.5 million less in collaboration revenue in 2009 and 2010, compared to amounts recognized in connection with these deferred payments in 2008. In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration, the Company also recognizes, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse.

The Company recognized $75.4 million, $67.3 million, and $31.2 million of collaboration revenue from Bayer HealthCare in 2010, 2009, and 2008, respectively. In both 2010 and 2009, collaboration revenue from Bayer HealthCare included $20.0 million in milestone payments, as described above, which, for the purpose of revenue recognition, were considered substantive. In addition, in 2010, 2009, and 2008, the Company recognized as additional research and development expense $48.9 million, $37.7 million, and $30.0 million, respectively, of VEGF Trap-Eye development expenses that the Company was obligated to reimburse to Bayer HealthCare.

At December 31, 2010, one $10.0 million milestone payment was receivable from Bayer HealthCare, as described above. In connection with cost-sharing of VEGF Trap-Eye expenses under the collaboration, $2.3 million and $1.2 million was payable to Bayer HealthCare at December 31, 2010 and 2009, respectively. In addition, at December 31, 2010 and 2009, deferred revenue from the Company's collaboration with Bayer HealthCare was $47.0 million and $56.8 million, respectively.

c. National Institute of Health

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. As amended, the NIH grant provides a minimum of $25.3 million in funding over a five-year period, including $1.5 million in funding to optimize certain existing technology, subject to compliance with its terms and annual funding approvals, for the Company's use of its *VelociGene®* technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells which can be used to produce knockout mice. The Company records revenue in connection with the NIH grant using a proportional performance model as it incurs expenses related to the grant, subject to the grant's terms and annual funding approvals. In 2010, 2009, and 2008, the Company recognized contract research revenue of $4.6 million, $5.5 million, and $4.9 million, respectively, from the NIH Grant.

4. Technology Licensing Agreements

In February 2007, the Company entered into a six-year, non-exclusive license agreement with AstraZeneca UK Limited to allow AstraZeneca to utilize the Company's *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million annual, non-refundable payment to the Company in each of 2010, 2009, 2008, and 2007. Each annual payment was deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement, effective in February 2011, thereby canceling its obligation to make either of the final two annual payments. Regeneron remains entitled to receive mid-single digit royalties on any future sales of antibody products discovered by MedImmune/AstraZeneca using the *VelocImmune®* technology.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3742

Samsung Bioepis Exhibit 1017, pg. 3742

In connection with the AstraZeneca license agreement, for each of the years ended December 31, 2010, 2009, and 2008, the Company recognized $20.0 million of technology licensing revenue. In addition, deferred revenue at December 31, 2010, 2009, and 2008 was $2.9 million.

In March 2007, the Company entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to the Company in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to the Company in August 2010, which was deferred upon receipt and will be recognized as revenue ratably over the seven-year period beginning in mid-2011. In addition, Astellas will make a $130.0 million second payment to the Company in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as a material breach of the agreement by the Company, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to the Company under the July 2010 amendment to the agreement. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune*® technology. In connection with the Astellas license agreement, for each of the years ended December 31, 2010, 2009, and 2008, the Company recognized $20.0 million of technology licensing revenue. In addition, deferred revenue at December 31, 2010, 2009, and 2008 was $173.7 million, $8.7 million, and $8.7 million, respectively.

5. ARCALYST® Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST® Injection for Subcutaneous Use for the treatment of CAPS. The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by $0.06 in 2010.

ARCALYST® net product sales totaled $25.3 million, $18.4 million, and $6.3 million for the years ended December 31, 2010, 2009, and 2008, respectively. ARCALYST® net product sales during 2010 included $20.5 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at December 31, 2010. At December 31, 2009, deferred ARCALYST® net product sales revenue was $4.8 million.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled $2.1 million, $1.7 million, and $0.9 million for the years ended December 31, 2010, 2009, and 2008, respectively. To date, ARCALYST® shipments to the Company's customers have primarily consisted of supplies of inventory manufactured and expensed as research and development costs prior to 2008; therefore, the costs of these supplies were not included in costs of goods sold. Inventories related to ARCALYST®, which were included in prepaid expenses and other current assets, consisted of $0.7 million of work-in-process and $0.1 million of finished goods at December 31, 2010, and $0.4 million of work-in-process at December 31, 2009.

6. Marketable Securities

Marketable securities at December 31, 2010 and 2009 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was $3.6 million and $5.5 million at December 31, 2010 and 2009, respectively, and the aggregate cost basis of which was $4.0 million at both December 31, 2010 and 2009. The Company also held restricted marketable securities at December 31, 2010, which consisted of debt securities, as detailed below, that collateralize (i) a letter of credit in connection with the Company's lease of facilities in Tarrytown, New York and (ii) capital lease obligations. See Note 11a. The Company held no restricted marketable securities at December 31, 2009.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3743

Samsung Bioepis Exhibit 1017, pg. 3743

The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at December 31, 2010 and 2009. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

At December 31, 2010	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Unrealized Net
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 83,635	$ 83,684	$ 54	$ (5)	$ 49
U.S. government guaranteed corporate bonds	48,173	48,531	358		358
U.S. government guaranteed collateralized mortgage obligations	2,027	2,131	104		104
Municipal bonds	1,597	1,603	6		6
Mortgage-backed securities	875	847		(28)	(28)
	136,307	136,796	522	(33)	489
Maturities between one and five years					
U.S. government obligations	352,345	350,683	64	(1,726)	(1,662)
U.S. government guaranteed corporate bonds	15,522	15,477		(45)	(45)
Mortgage-backed securities	110	38		(72)	(72)
	367,977	366,198	64	(1,843)	(1,779)
Maturities between five and seven years					
Mortgage-backed securities	284	243		(41)	(41)
	504,568	503,237	586	(1,917)	(1,331)
Restricted					
Maturities within one year					
U.S. government obligations	2,922	2,921		(1)	(1)
Maturities between one and three years					
U.S. government obligations	4,135	4,118		(17)	(17)
	7,057	7,039		(18)	(18)
	$511,625	$510,276	$ 586	$(1,935)	$(1,349)

At December 31, 2009					
Unrestricted					
Maturities within one year					
U.S. government obligations	$100,491	$100,573	$ 82		$ 82
U.S. government guaranteed corporate bonds	17,176	17,340	164		164
Corporate bonds	10,142	10,342	200		200
U.S. government guaranteed collateralized mortgage obligations	3,612	3,662	50		50
Mortgage-backed securities	2,471	2,338		$ (133)	(133)
	133,892	134,255	496	(133)	363
Maturities between one and two years					
U.S. government obligations	9,413	9,367		(46)	(46)
U.S. government guaranteed corporate bonds	31,064	31,344	280		280
Mortgage-backed securities	1,168	900		(268)	(268)
	41,645	41,611	280	(314)	(34)
	$175,537	$175,866	$ 776	$ (447)	$ 329

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3744

Samsung Bioepis Exhibit 1017, pg. 3744

At December 31, 2010 and 2009, marketable securities included an additional unrealized loss of $0.4 million and an additional unrealized gain of $1.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at December 31, 2010 and 2009. The debt securities listed at December 31, 2010, excluding mortgage-backed securities, mature at various dates through November 2013. The mortgage-backed securities listed at December 31, 2010 mature at various dates through January 2017.

	Less than 12 Months		12 Months or Greater		Total	
At December 31, 2010	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Unrestricted						
U.S. government obligations	$ 340,444	$ (1,731)			$ 340,444	$ (1,731)
U.S. government guaranteed corporate bonds	19,005	(45)			19,005	(45)
Equity security	3,612	(433)			3,612	(433)
Mortgage-backed securities			$ 1,128	$ (141)	1,128	(141)
	363,061	(2,209)	1,128	(141)	364,189	(2,350)
Restricted						
U.S. government obligations	6,154	(18)			6,154	(18)
	6,154	(18)			6,154	(18)
	$ 369,215	$ (2,227)	$ 1,128	$ (141)	$ 370,343	$ (2,368)
At December 31, 2009						
U.S. government obligations	$ 9,367	$ (46)			$ 9,367	$ (46)
Mortgage-backed securities			$ 3,238	$ (401)	3,238	(401)
	$ 9,367	$ (46)	$ 3,238	$ (401)	$ 12,605	$ (447)

Realized gains and losses are included as a component of investment income. For the year ended December 31, 2010, realized losses on sales of marketable securities totaled $0.2 million and realized gains on sales of marketable securities were not significant. For the years ended December 31, 2009 and 2008, realized gains on sales of marketable securities totaled $0.2 million and $1.2 million, respectively, and realized losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3745

Samsung Bioepis Exhibit 1017, pg. 3745

The Company's assets that are measured at fair value on a recurring basis, at December 31, 2010 and 2009, were as follows:

		Fair Value Measurements at Reporting Date Using		
	Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At December 31, 2010				
Unrestricted				
Available-for-sale marketable securities				
U.S. government obligations	$ 434,567		$ 434,567	
U.S. government guaranteed corporate bonds	64,008		64,008	
U.S. government guaranteed collateralized mortgage obligations	2,131		2,131	
Municipal bonds	1,603		1,603	
Mortgage-backed securities	1,128		1,128	
Equity security	3,612	$ 3,612		
	506,849	3,612	503,237	
Restricted				
Available-for-sale marketable securities				
U.S. government obligations	7,039		7,039	
	$ 513,888	$ 3,612	$ 510,276	
At December 31, 2009				
Available-for-sale marketable securities				
U.S. government obligations	$ 109,940		$ 109,940	
U.S. government guaranteed corporate bonds	48,684		48,684	
Corporate bonds	10,342		10,342	
U.S. government guaranteed collateralized mortgage obligations	3,662		3,662	
Mortgage-backed securities	3,238		3,238	
Equity security	5,469	$ 5,469		
	$ 181,335	$ 5,469	$ 175,866	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During each of the years ended December 31, 2010 and 2008, deterioration in the credit quality of a marketable security subjected the Company to the risk of not being able to recover the carrying value of these securities. As a result, the Company recognized a $0.1 million and $1.8 million impairment charge related to its Level 2 marketable securities for the years ended December 31, 2010 and 2008, respectively, which the Company considered to be other-than-temporarily impaired. During the year ended December 31, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3746

Samsung Bioepis Exhibit 1017, pg. 3746

The Company held one Level 3 marketable security, which had no fair value at December 31, 2010 and 2009, and whose fair value was $0.1 million at December 31, 2008. This Level 3 security was valued using information provided by the Company's investment advisors and other sources, including quoted bid prices which took into consideration the securities' lack of liquidity. During the years ended December 31, 2009 and 2008, the Company recorded charges of $0.1 million and $0.7 million, respectively, for other-than-temporary impairment of this Level 3 marketable security; therefore, as of December 31, 2009, the fair value of this security had been written down to zero. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the years ended December 31, 2010 and 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the years ended December 31, 2010 and 2009.

As described in Note 2 above under "Use of Estimates", on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

7. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2010 and 2009 consist of the following:

	2010	2009
Land	$ 2,117	$ 2,117
Building and improvements	242,035	177,710
Leasehold improvements	4,063	4,023
Construction-in-progress	70,356	58,541
Laboratory and other equipment	137,951	114,099
Furniture, computer and office equipment, and other	22,235	15,964
	478,757	372,434
Less, accumulated depreciation and amortization	(131,307)	(112,778)
	$ 347,450	$ 259,656

Depreciation and amortization expense on property, plant, and equipment amounted to $19.7 million, $14.2 million, and $10.6 million for the years ended December 31, 2010, 2009, and 2008, respectively. Effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, were extended. The effect of this change in estimate was to lower depreciation expense by $4.0 million and to lower the Company's net loss per share by $0.05 for the year ended December 31, 2010.

Included in property, plant, and equipment at December 31, 2010 was $2.8 million of leased equipment under capital leases (see Note 11a); related accumulated amortization was $0.1 million at December 31, 2010. The Company held no leased equipment under capital leases at December 31, 2009.

Building and improvements at December 31, 2010 and 2009 includes $58.4 million and $58.2 million, respectively, of costs incurred by the Company's landlord to construct new laboratory and office facilities in Tarrytown, New York in connection with the Company's December 2006 lease, as amended, of these new facilities. In addition, construction-in-progress at both December 31, 2010 and 2009 includes $27.8 million of costs incurred by the Company's landlord in connection with these new facilities. See Note 11a.

The Company capitalized interest costs of $6.4 million and $0.5 million in 2010 and 2009, respectively. The Company did not capitalize any interest costs in 2008.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3747

Samsung Bioepis Exhibit 1017, pg. 3747

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2010 and 2009 consist of the following:

	2010	2009
Accounts payable	$15,589	$18,638
Accrued payroll and related costs	12,025	9,444
Accrued clinical trial expense	9,727	11,673
Accrued property, plant, and equipment costs	7,622	1,883
Other accrued expenses and liabilities	6,441	6,207
Payable to Bayer HealthCare	2,254	1,186
	$53,658	$49,031

9. Deferred Revenue

Deferred revenue as of December 31, 2010 and 2009 consists of the following:

	2010	2009
Current portion:		
Received from sanofi-aventis (see Note 3a)	$ 19,506	$ 17,523
Received from Bayer HealthCare (see Note 3b)	9,884	9,884
Received for technology license agreements (see Note 4)	25,008	11,579
Other	325	5,558
	$ 54,723	$ 44,544
Long-term portion:		
Received from sanofi-aventis (see Note 3a)	$ 97,081	$ 90,933
Received from Bayer HealthCare (see Note 3b)	37,067	46,951
Received for technology license agreements (see Note 4)	151,708	
	$285,856	$137,884

10. Convertible Debt

In October 2001, the Company issued $200.0 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company of $192.7 million, after deducting the initial purchasers' discount and out-of-pocket expenses (collectively, "Deferred Financing Costs"). The Notes bore interest at 5.5% per annum, payable semi-annually, and matured on October 17, 2008. Deferred Financing Costs, which were included in other assets, were amortized as interest expense over the period from the Notes' issuance to stated maturity. During the second and third quarters of 2008, the Company repurchased $82.5 million in principal amount of the Notes for $83.3 million and recognized a $0.9 million loss on early extinguishment of debt, representing the premium paid on the Notes plus related unamortized Deferred Financing Costs. The remaining $117.5 million of outstanding Notes were repaid in full upon their maturity in October 2008.

11. Commitments and Contingencies

a. Leases

Descriptions of Lease Agreements

The Company leases laboratory and office facilities in Tarrytown, New York, under a December 2006 lease agreement, as amended (the "Tarrytown Lease"). The facilities leased by the Company under the Tarrytown Lease include (i) space in previously existing buildings, (ii) newly constructed space in two new buildings ("Buildings A and B") that was completed during the third quarter of 2009 and, (iii) under a December 2009 amendment to

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3748

Samsung Bioepis Exhibit 1017, pg. 3748

the Tarrytown Lease, additional new space that is under construction in a third new building ("Building C") and expected to be completed in the first quarter of 2011. The Tarrytown Lease will expire in June 2024 and contains three renewal options to extend the term of the lease by five years each, escalations at 2.5% per annum, and early termination options for various portions of the space exclusive of the newly constructed space in Buildings A and B. The Tarrytown Lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Certain premises under the Tarrytown Lease are accounted for as operating leases. However, for Buildings A, B, and C that the Company is leasing, the Company is deemed, in substance, to be the owner of the landlord's buildings in accordance with the application of FASB authoritative guidance, and the landlord's costs of constructing these new facilities are required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet.

In connection with the Tarrytown Lease, at lease inception, the Company issued a letter of credit in the amount of $1.6 million to its landlord, which was collateralized by a $1.6 million bank certificate of deposit at December 31, 2009. During 2010, the Company increased this letter of credit to $3.4 million, in accordance with the provisions of the Tarrytown Lease, and collateralized the letter of credit with cash and marketable debt securities totaling $3.6 million. Such collateral at December 31, 2010 and 2009 has been classified as restricted cash and marketable securities.

In October 2008, the Company entered into a sublease with sanofi-aventis U.S. Inc. for office space in Bridgewater, New Jersey. The lease commenced in January 2009 and expires in July 2011. The Company also formerly leased additional office space in Tarrytown, New York under operating subleases that ended at various times through September 2009.

The Company also leases certain laboratory and office equipment under operating and capital leases which expire at various times through 2013.

Commitments under Operating Leases

The estimated future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2011	$ 6,098	$225	$ 6,323
2012	5,468	118	5,586
2013	6,617	24	6,641
2014	6,733		6,733
2015	6,866		6,866
Thereafter	64,196		64,196
	$95,978	$367	$96,345

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
2010	$7,301	$335	$7,636
2009	7,722	395	8,117
2008	6,530	416	6,946

In addition to its rent expense for various facilities, the Company paid rental charges for utilities, real estate taxes, and operating expenses of $10.3 million, $8.4 million, and $8.4 million for the years ended December 31, 2010, 2009, and 2008, respectively.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3749

Samsung Bioepis Exhibit 1017, pg. 3749

Commitments under Capital Leases

In 2010, the Company entered into capital leases in connection with acquisitions of new equipment. The lease obligations are collateralized with marketable debt securities totaling $3.5 million; such collateral has been classified as restricted cash and marketable securities at December 31, 2010.

The estimated future minimum noncancelable lease commitments under capital leases were as follows:

December 31,	Equipment
2011	$1,137
2012	1,135
2013	995
Total minimum lease payments	3,267
Less: amount representing interest	(438)
	$2,829

At the end of the lease term, the Company is required to purchase the leased equipment for a nominal amount defined in the lease agreement. At December 31, 2010, capital lease obligations totaling $2.8 million were included in other liabilities. There were no capital lease obligations at December 31, 2009. As of December 31, 2010, the Company had $0.7 million of financing available under a capital equipment lease line.

Facility Lease Obligations

As described above, in connection with the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Buildings A and B, the Company capitalized the landlord's costs of constructing the new facilities, which totaled $58.4 million as of December 31, 2010, and recognized a corresponding facility lease obligation of $58.4 million. The Company also recognized, as additional facility lease obligation, reimbursements totaling $56.9 million from the Company's landlord during 2010 and 2009 for tenant improvement costs that the Company incurred since, under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. The new facilities were placed in service by the Company in September 2009. For the years ended December 31, 2010 and 2009, the Company recognized in its statement of operations $9.1 million and $2.3 million, respectively, of interest expense in connection with the facility lease obligation. At December 31, 2010 and 2009, the facility lease obligation balance in connection with Buildings A and B was $113.7 million and $81.0 million, respectively.

In addition, as described above, in December 2009, the Company amended its December 2006 agreement to lease additional new laboratory and office facilities in Building C that is under construction. In connection with the application of FASB authoritative guidance to the Company's lease of these additional new facilities, the Company is deemed, in substance, to be the owner of the landlord's building, and the landlord's costs of constructing Building C is required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet. As of December 31, 2010, the Company capitalized $27.8 million of the landlord's costs of constructing Building C, and recognized a corresponding facility lease obligation of $27.8 million. The Company also recognized, as additional facility lease obligation, reimbursements totaling $14.2 million from the Company's landlord during 2010 for tenant improvement costs that the Company incurred since, under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation. Monthly lease payments on these facilities will commence in January 2011. Rent expense in connection with the land element of these additional facilities, which is accounted for as an operating lease, commenced in December 2009 and is recorded as a deferred liability until lease payments commence in January 2011. In addition, interest expense is imputed at a rate of approximately 9%, and is capitalized and deferred in connection with this facility lease obligation. At December 31, 2010 and 2009, the facility lease obligation balance in connection with Building C was $46.4 million and $28.0 million, respectively.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3750

Samsung Bioepis Exhibit 1017, pg. 3750

The estimated future minimum noncancelable commitments under these facility lease obligations, as of December 31, 2010, were as follows:

December 31,	Buildings A and B	Building C	Total
2011	$ 11,347	$ 2,468	$ 13,815
2012	12,603	2,767	15,370
2013	12,843	4,285	17,128
2014	13,090	4,403	17,493
2015	13,343	4,524	17,867
Thereafter	124,515	43,783	168,298
	$187,741	$62,230	$249,971

b. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with related and unrelated companies, scientific collaborators, universities, and consultants. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company, services to be provided, and ownership rights to certain proprietary technology developed under the agreements. Some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.25% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

Certain agreements under which the Company is required to pay fees permit the Company, upon 30 to 90-day written notice, to terminate such agreements. With respect to payments associated with these agreements, the Company incurred expenses of $1.6 million, $2.8 million, and $3.5 million for the years ended December 31, 2010, 2009, and 2008, respectively.

In connection with the Company's receipt of marketing approval from the FDA for ARCALYST® for the treatment of CAPS, in 2008, the Company commenced paying royalties under various licensing agreements based on ARCALYST® net product sales. For the years ended December 31, 2010, 2009, and 2008, ARCALYST® royalties totaled $1.7 million, $1.5 million, and $0.6 million, respectively, and are included in cost of goods sold.

In July 2008, the Company and Cellectis S.A. ("Cellectis") entered into an Amended and Restated Non-Exclusive License Agreement (the "Cellectis Agreement"). The Cellectis Agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which the Company licensed certain patents and patent applications from Cellectis. Pursuant to the Cellectis Agreement, in July 2008, the Company made a non-refundable $12.5 million payment to Cellectis (the "Cellectis Payment") and agreed to pay Cellectis a low single-digit royalty based on revenue received by the Company from any future licenses or sales of the Company's *VelociGene*® or *VelocImmune*® products and services. No royalties are payable to Cellectis with respect to the Company's *VelocImmune*® license agreements with AstraZeneca and Astellas or the Company's antibody collaboration with sanofi-aventis. Moreover, no royalties are payable to Cellectis on any revenue from commercial sales of antibodies from the Company's *VelocImmune*® technology.

The Company began amortizing the Cellectis Payment in the second quarter of 2008 in proportion to past and future anticipated revenues under the Company's license agreements with AstraZeneca and Astellas and the Discovery and Preclinical Development Agreement under the Company's antibody collaboration with sanofi-aventis (as amended in November 2009). In 2010, 2009, and 2008, the Company recognized $0.9 million, $2.3 million, and $2.7 million, respectively, of expense in connection with the Cellectis Payment. At December 31, 2010 and 2009, the unamortized balance of the Cellectis Payment, which was included in other assets, was $6.6 million and $7.6 million, respectively. The Company estimates that it will recognize expense of $1.0 million in each of 2011, 2012, and 2013, and $0.9 million in each of 2014 and 2015, in connection with the Cellectis Payment.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3751

Samsung Bioepis Exhibit 1017, pg. 3751

12. Stockholders Equity

The Company's Restated Certificate of Incorporation provides for the issuance of up to 40 million shares of Class A Stock, par value $0.001 per share, and 160 million shares of Common Stock, par value $0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's board of directors is authorized to issue up to 30 million shares of preferred stock, in series, with rights, privileges, and qualifications of each series determined by the board of directors.

In September 2003, sanofi-aventis purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for $45.0 million. See Note 3.

In December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for an aggregate cash price of $312.0 million. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with the Company, which was amended in November 2009. Under the amended investor agreement, sanofi-aventis has three demand rights to require the Company to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Company's Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the License and Collaboration Agreement, as amended in 2009, under the Company's antibody collaboration with sanofi-aventis (see Note 3) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept (see Note 3), sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of the Company's Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Under the amended investor agreement, sanofi-aventis has also agreed not to dispose of any shares of the Company's Common Stock that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2017, subject to certain limited exceptions. Following December 20, 2017, sanofi-aventis will be permitted to sell shares of the Company's Common Stock (i) in a registered underwritten public offering undertaken pursuant to the demand registration rights granted to sanofi-aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of the Company's Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or more of the outstanding shares of the Company's Common Stock, and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by the Company's board of directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of the Company's voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by the Company's board of directors or proportionally with the votes cast by the Company's other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of the Company's Class A Stock and Common Stock, and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

In October 2010, the Company completed an underwritten public offering of 6,325,000 shares of Common Stock and received net proceeds of $174.8 million. Sanofi-aventis purchased 1,017,401 shares of Common Stock in this offering.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3752

Samsung Bioepis Exhibit 1017, pg. 3752

13. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan which, as amended and restated (the "2000 Incentive Plan"), provides for the issuance of up to 29,307,016 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant. The maximum term of options that have been awarded under the 2000 Incentive Plan is ten years.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the Restricted Stock, which has not vested, will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts, if any, paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

Phantom Stock awards provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of the Company's Common Stock as determined by the Committee, equal to the sum of the fair market value of a share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests. Stock Bonus awards are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Company's Common Stock. Subject to the provisions of the 2000 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

The 2000 Incentive Plan contains provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined in the plan.

As of December 31, 2010, there were 434,564 shares available for future grants under the 2000 Incentive Plan.

During 1990, the Company established the 1990 Incentive Plan which, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, received awards as determined by a committee of independent directors. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. Awards under the 1990 Incentive Plan consisted of Incentive Stock Options and Nonqualified Stock Options which generally vested on a pro rata basis over a three or five year period and had a term of ten years.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3753

Samsung Bioepis Exhibit 1017, pg. 3753

a. Stock Options

Transactions involving stock option awards during 2010 under the 1990 and 2000 Incentive Plans are summarized in the table below.

Stock Options:	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Intrinsic Value (in thousands)
Outstanding at December 31, 2009	21,788,755	$18.45		
2010: Granted	4,319,856	$29.43		
Forfeited	(183,252)	$20.22		
Expired	(887,281)	$38.63		
Exercised	(1,675,830)	$15.24		
Outstanding at December 31, 2010	23,362,248	$19.93	6.47	$308,766
Vested and expected to vest at December 31, 2010	22,803,097	$19.81	6.38	$304,116
Exercisable at December 31, 2010	12,910,390	$17.54	4.91	$201,662

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2010, 2009, and 2008 was $21.4 million, $13.2 million, and $11.9 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The Company grants stock options with exercise prices that are equal to or greater than the average market price of the Company's Common Stock on the date of grant ("Market Price"). The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2010, 2009, and 2008. The fair value of each option granted under the 2000 Incentive Plan during 2010, 2009, and 2008 was estimated on the date of grant using the Black-Scholes option-pricing model.

	Number of Options Granted	Weighted-Average Exercise Price	Weighted-Average Fair Value
2010:			
Exercise price equal to Market Price	4,319,856	$29.43	$13.36
2009:			
Exercise price equal to Market Price	3,490,560	$20.69	$10.89
2008:			
Exercise price equal to Market Price	4,126,600	$17.38	$ 8.45

For the years ended December 31, 2010, 2009, and 2008, $29.4 million, $27.4 million, and $30.3 million, respectively, of non-cash stock-based compensation expense related to non-performance based stock option awards was recognized in operating expenses. As of December 31, 2010, there was $57.5 million of stock-based compensation cost related to outstanding non-performance based stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years.

In addition, there were 2,486,510 performance-based options which were unvested as of December 31, 2010 of which, subject to the optionee satisfying certain service conditions, 664,760 options that were issued in 2005 would vest upon achieving certain defined sales targets for the Company's products and 1,821,750 options that were issued in 2008, 2009, and 2010 would vest upon achieving certain development milestones for the Company's product candidates. In light of the status of the Company's development programs at December 31, 2010, the Company estimates that all of the performance-based options issued in 2008, 2009, and 2010 will vest since the Company

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3754

Samsung Bioepis Exhibit 1017, pg. 3754

considers these options' performance conditions to be probable of attainment. Principally as a result, in 2010, the Company recognized $8.1 million of non-cash stock-based compensation expense related to these performance options. In light of the status of the Company's development programs at December 31, 2009, the Company estimated that approximately two-thirds of the performance-based options issued in 2008 and 2009 would vest; therefore, in 2009, the Company recognized $1.7 million of non-cash stock-based compensation expense, related to these performance-based options. As of December 31, 2010, there was $17.6 million of stock-based compensation cost which had not yet been recognized in operating expenses related to the performance-based options that the Company currently estimates will vest. The Company expects to recognize this compensation cost over a weighted-average period of 2 years. In addition, potential compensation cost of $2.5 million related to the performance options issued in 2005, whose performance conditions (based on current facts and circumstances) are not currently considered by the Company to be probable of attainment, will begin to be recognized only if, and when, the Company estimates that it is probable that these options will vest. The Company's estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods. Changes in these estimates may materially affect the amount of stock-based compensation recognized in future periods related to performance-based options.

Fair value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2010, 2009, and 2008.

	2010	2009	2008
Expected volatility	47%	54%	53%
Expected lives from grant date	5.6 years	5.9 years	5.5 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	2.11%	2.87%	1.73%

Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's historical exercise experience with previously issued employee and board of directors option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives.

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the year ended December 31, 2010 is summarized below:

Restricted Stock:	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2009	500,000	$21.92
2010: Granted	345,000	$30.37
Outstanding at December 31, 2010	845,000	$25.37

The Company recognized non-cash stock-based employee compensation expense from Restricted Stock awards of $2.4 million, $2.2 million, and $2.2 million in 2010, 2009, and 2008, respectively. As of December 31, 2010, there were 845,000 unvested shares of Restricted Stock outstanding and $14.6 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 2.4 years.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3755

Samsung Bioepis Exhibit 1017, pg. 3755

14. Executive Stock Purchase Plan

In 1989, the Company adopted an Executive Stock Purchase Plan (the "Plan") under which 1,027,500 shares of Class A Stock were reserved for restricted stock awards. The Plan provides for the compensation committee of the board of directors to award employees, directors, consultants, and other individuals ("Plan participants") who render service to the Company the right to purchase Class A Stock at a price set by the compensation committee. The Plan provides for the vesting of shares as determined by the compensation committee and, should the Company's relationship with a Plan participant terminate before all shares are vested, unvested shares will be repurchased by the Company at a price per share equal to the original amount paid by the Plan participant. During 1989 and 1990, a total of 983,254 shares were issued, all of which vested as of December 31, 1999. As of December 31, 2010, there were 44,246 shares available for future grants under the Plan.

15. Employee Savings Plan

In 1993, the Company adopted the provisions of the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan provide for employees who have met defined service requirements to participate in the Savings Plan by electing to contribute to the Savings Plan a percentage of their compensation to be set aside to pay their future retirement benefits, as defined. The Savings Plan, as amended and restated, provides for the Company to make discretionary contributions ("Contribution"), as defined. The Company recognized $3.2 million, $2.6 million, and $1.5 million of Contribution expense in 2010, 2009, and 2008, respectively. At December 31, 2010 and 2009, accrued Contribution expense totaled $2.9 million and $2.6 million, respectively. During the first quarter of 2011 and 2010, the Company contributed 91,761 and 111,419 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

16. Income Taxes

For the year ended December 31, 2010, the Company incurred a net loss for tax purposes and recognized a full valuation allowance against deferred taxes. Accordingly, no provision or benefit for income taxes was recorded in 2010.

For the year ended December 31, 2009, the Company incurred a net loss for tax purposes and recognized a full valuation allowance against deferred taxes. In 2009, the Company recognized a $4.1 million income tax benefit, consisting of (i) $2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allows the Company to claim a refund of U.S. federal alternative minimum tax ("AMT") that the Company paid in connection with its 2007 U.S. federal income tax return, as described below, (ii) $0.7 million income tax benefit resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allows the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2009 U.S. federal income tax return, and (iii) $0.7 million income tax benefit in connection with the net tax effect of the Company's unrealized gain on "available-for-sale" marketable securities, which is included in other comprehensive income in 2009.

For the year ended December 31, 2008, the Company incurred a net loss for tax purposes and recognized a full valuation allowance against deferred taxes. During 2008, the Company implemented a tax planning strategy to utilize net operating loss carry-forwards (which were otherwise due to expire in 2008 through 2012) on its 2007 U.S. federal and New York State income tax returns that were filed in September 2008. The tax planning strategy included electing, for tax purposes only, to capitalize $142.1 million of 2007 research and development ("R&D") costs and amortize these costs over ten years for tax purposes. By capitalizing these R&D costs, the Company was able to generate taxable income for tax year 2007 and utilize the net operating loss carry-forwards to offset this taxable income. As a result, the Company incurred and paid income tax expense of $3.1 million in 2008, which related to U.S. federal and New York State AMT and included $0.2 million of interest and penalties. This expense was partly offset by the Company's recognition of a $0.7 million income tax benefit in 2008, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2008 U.S federal income tax return.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3756

Samsung Bioepis Exhibit 1017, pg. 3756

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental and other tax credit carry-forwards as of December 31, 2010 and 2009 is as follows:

	2010	2009
Deferred tax assets:		
Net operating loss carry-forward	$ 243,893	$ 200,266
Fixed assets	13,600	13,833
Deferred revenue	70,443	73,865
Deferred compensation	39,120	29,736
Research and experimental and other tax credit carry-forwards	45,588	22,377
Capitalized research and development costs	38,865	49,107
Other	10,863	10,142
Valuation allowance	(462,372)	(399,326)
	—	—

The Company's valuation allowance increased by $63.0 million in 2010, due primarily to increases in the net operating loss carry-forward and tax credit carry-forwards. In 2009, the Company's valuation allowance increased by $19.0 million, due primarily to the increase in the net operating loss carry-forward.

The Company is primarily subject to U.S. federal and New York State income tax. The difference between the Company's effective income tax rate and the U.S federal statutory rate of 35% is primarily attributable to an increase in the deferred tax valuation allowance. Due to the Company's history of losses, all tax years remain open to examination by U.S. federal and state tax authorities. In January 2011, U.S. federal tax authorities commenced an examination of the Company's 2007 and 2008 U.S. federal income tax returns.

As of December 31, 2010 and 2009, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2010, the Company had available for tax purposes unused net operating loss carry-forwards of $614.9 million which will expire in various years from 2018 to 2030 and included $7.1 million of net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of Incentive Stock Options, the tax benefit from which, if realized, will be credited to additional paid-in capital. The Company's research and experimental and other tax credit carry-forwards expire in various years from 2011 to 2030. Under the Internal Revenue Code and similar state provisions, substantial changes in the Company's ownership have resulted in an annual limitation on the amount of net operating loss and tax credit carry-forwards that can be utilized in future years to offset future taxable income. This annual limitation may result in the expiration of net operating losses and tax credit carry-forwards before utilization.

The following table summarizes the gross amounts of unrecognized tax benefits at the beginning and end of 2010:

	2010
Balance as of January 1	$ —
Gross increases related to current year tax positions	3,550
Gross increases related to prior year tax positions	9,269
Balance as of December 31	$12,819

In 2010, the gross increases in unrecognized tax benefits related to prior year tax positions was primarily due to the Company's calculations of certain pre-2010 tax credits. Due to the amounts of the Company's net operating loss carry-forward and tax credit carry-forwards, the Company has not accrued interest or penalties related to these unrecognized tax benefits. In addition, unrecognized tax benefits at December 31, 2010, if recognized, would not affect the Company's effective tax rate since the adjustments to deferred tax assets would be fully offset by

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3757

Samsung Bioepis Exhibit 1017, pg. 3757

adjustments to the Company's valuation allowance. For the years ended December 31, 2009 and 2008, income tax positions that were deemed uncertain under the recognition thresholds and measurement attributes prescribed in FASB authoritative guidance were not significant.

17. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition. Legal costs associated with the Company's resolution of legal proceedings are expensed as incurred.

On November 19, 2010, the Company filed a complaint against Genentech, Inc. in the United States District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint. The motion is currently pending. The Company may initiate similar actions in countries outside the United States.

18. Net Loss Per Share Data

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. In 2010, 2009, and 2008, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	December 31,		
	2010	2009	2008
Net loss (Numerator)	$(104,468)	$(67,830)	$(79,129)
Weighted-average shares, in thousands (Denominator)	82,926	79,782	78,827
Basic and diluted net loss per share	$ (1.26)	$ (0.85)	$ (1.00)

Shares issuable upon the exercise of options and vesting of restricted stock awards, which have been excluded from the diluted per share amounts because their effect would have been antidilutive, include the following:

	December 31,		
	2010	2009	2008
Options:			
Weighted average number, in thousands	21,428	20,040	17,598
Weighted average exercise price	$ 18.80	$ 17.66	$ 17.31
Restricted Stock:			
Weighted average number, in thousands	526	500	500

19. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at December 31, 2010, 2009, and 2008 were $10.7 million, $9.8 million, and $7.0 million of accrued capital expenditures, respectively.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3758

Samsung Bioepis Exhibit 1017, pg. 3758

Included in accounts payable and accrued expenses at December 31, 2009, 2008, and 2007 were $2.6 million, $1.5 million, and $1.1 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2010, 2009, and 2008, the Company contributed 111,419, 81,086, and 58,575 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Pursuant to the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Tarrytown, New York (see Note 11a), the Company recognized a facility lease obligation of $0.2 million and $31.7 million during 2010 and 2009, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in facility lease obligations and property, plant, and equipment at December 31, 2010 was $3.7 million of capitalized and deferred interest for the year ended December 31, 2010, as the related facilities being leased by the Company are currently under construction and lease payments on these facilities do not commence until January 2011.

The Company incurred capital lease obligations of $2.9 million during 2010 in connection with acquisitions of new equipment.

Included in other assets at December 31, 2010 and 2009 was $0.2 million and $0.7 million, respectively, due to the Company in connection with employee exercises of stock options in December 2010.

Included in marketable securities at December 31, 2010, 2009, and 2008 were $1.4 million, $0.6 million, and $1.7 million of accrued interest income, respectively.

20. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2010 and 2009 are set forth in the following tables.

	First Quarter Ended March 31, 2010	Second Quarter Ended June 30, 2010	Third Quarter Ended September 30, 2010	Fourth Quarter Ended December 31, 2010
	(Unaudited)			
Revenues	$103,531	$115,886	$105,979	$133,675
Net loss	(30,522)	(25,474)	(33,875)	(14,597)
Net loss per share, basic and diluted	$ (0.38)	$ (0.31)	$ (0.41)	$ (0.17)

	First Quarter Ended March 31, 2009	Second Quarter Ended June 30, 2009	Third Quarter Ended September 30, 2009	Fourth Quarter Ended December 31, 2009
	(Unaudited)			
Revenues	$ 74,981	$ 90,032	$117,455	$ 96,800
Net loss	(15,388)	(14,938)	(1,015)	(36,489)
Net loss per share, basic and diluted	$ (0.19)	$ (0.19)	$ (0.01)	$ (0.46)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3759

Samsung Bioepis Exhibit 1017, pg. 3759

Exhibit 10.1.7

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

Notice of Grant of Award
And Award Agreement

[NAME]
[ADDRESS]

Award Number: [ ]
Plan: 04

Effective <**date**> (the "Grant Date") you have been granted an award of [ ] shares of Regeneron Pharmaceuticals, Inc. (the Company) common stock. These shares are restricted until the vest date(s) shown below.

The current total value of the award is [$].

The award will vest on the date(s) shown.

Shares	**Full Vest**
[ ]*	[ ]*
[ ]*	[ ]*
[ ]*	[ ]*

You and the Company agree that this award is granted under and governed by the terms and conditions of the Company's 2000 Long-Term Incentive Plan as amended and the Award Agreement, both of which are attached and made a part of this document.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3760

Samsung Bioepis Exhibit 1017, pg. 3760

REGENERON PHARMACEUTICALS, INC.

RESTRICTED STOCK AGREEMENT
PURSUANT TO THE
2000 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT, made as of the date on the *Notice of Grant of Restricted Stock*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Restricted Stock* (the "Recipient");

WHEREAS, the Recipient is an employee of the Company and the Company desires to afford the Recipient the opportunity to acquire or enlarge the Recipient's stock ownership in the Company so that the Recipient may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the 2000 Long-Term Incentive Plan (the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Restricted Stock*) to the Recipient the shares of Restricted Stock as set forth in the *Notice of Grant of Restricted Stock*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 8 of the Plan, the Company grants to the Recipient, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the number of shares of Restricted Stock as shown on the *Notice of Grant of Restricted Stock*. The Participant's grant and record of Restricted Stock share ownership shall be kept on the books of the Company until the restrictions on transfer have lapsed. At the Recipient's request, vested shares may be evidenced by stock certificates.

2. Vesting. (a) The shares of Restricted Stock granted to the Recipient shall vest in installments as provided in the *Notice of Grant of Restricted Stock*. The vesting schedule in the *Notice of Grant of Restricted Stock* indicates each date upon which the restrictions on transfer on the specified number of shares of Restricted Stock shall lapse, entitling the Recipient to freely transfer such shares, provided that the Recipient has not incurred a termination of employment with the Company and all Subsidiaries (collectively, the Company and its Subsidiaries shall be referred to herein as the "Employer"). There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Restricted Stock* and all vesting shall occur only on the Full Vest Dates. Except as set forth in the Plan or in any employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the grant date specified in the *Notice of Grant of Restricted Stock*, no vesting shall occur after the termination of a Recipient's employment with the Employer for any reason.

(b) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Restricted Stock* to the contrary, the Restricted Stock granted to Recipient shall be fully vested on the date the Recipient's employment with the Employer is terminated if the Recipient's employment with the Employer is terminated (i) by the Company (other than for Cause) or (ii) by the Recipient for Good Reason (provided that such termination for Good Reason occurs on or within two years after the occurrence of a Change in Control). Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date of grant specified in the *Notice of Grant of Restricted Stock*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment (collectively, the "Company Payments") would result in the Recipient being subject to excise tax payable under Internal Revenue Code Section 4999 (the "Excise Tax") , the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Recipient to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Recipient (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Recipient minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Recipient or, in the event the parties cannot agree, in the following order (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur, (2) any lump sum severance based on a multiple of base salary or bonus, (3) any other cash amounts payable to the Recipient, (4) any benefits valued as parachute payments, and (5) acceleration of vesting of any equity not covered by (1) above.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3761

Samsung Bioepis Exhibit 1017, pg. 3761

(c) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date of grant specified in the *Notice of Grant of Restricted Stock* (or where there is such an agreement but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Recipient substantially to perform his or her duties and obligations to the Employer, including without limitation, repeated refusal to follow the reasonable directions of the Employer, knowing violation of law in the course of performance of the duties of the Recipient's employment with the Employer, repeated absences from work without a reasonable excuse, and intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours (other than any such failure resulting from his or her incapacity due to physical or mental illness); (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date of grant specified on the *Notice of Grant of Restricted Stock* that defines "cause" (or words of like import), as defined under such agreement. For purposes of this Section 3(c), no act, or failure to act, on a Recipient's part shall be considered "willful" unless done, or omitted to be done, by the Recipient in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

(d) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date of grant specified in the *Notice of Grant of Restricted Stock* (or where there is such an agreement but it does not define "good reason" (or words of like import)) a termination of employment by the Recipient within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Recipient to the Employer that Recipient intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Recipient's duties and responsibilities from that which exists immediately prior to a Change in Control (except in each case in connection with the termination of the Recipient's employment for Cause or as a result of the Recipient's death, or temporarily as a result of the Recipient's illness or other absence), or (2) the assignment to the Recipient of duties and responsibilities materially inconsistent with the position held by the Recipient; (B) any material breach by the Employer of any material provision of any written agreement with the Recipient or failure to timely pay any compensation obligation to the Recipient; (C) a reduction in the Recipient's annual base salary or target bonus opportunity (if any) from that which exists immediately prior to a Change in Control; or (D) if the Recipient is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Recipient's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date on the *Notice of Grant of Restricted Stock* that defines "good reason" (or words of like import), as defined under such agreement.

3. Termination of Service. Subject to the terms of the Plan and Section 2(b), if the Recipient's employment with the Company is terminated for any reason (other than as set forth in Section 2(b) and as a result of Recipient's death or Disability), the Recipient shall forfeit any or all of the shares of Restricted Stock that have not vested in accordance with Section 2 hereof (the "Unvested Shares"). Shares of Restricted Stock granted to the Recipient in the Notice of Grant of Restricted Stock shall become fully vested as of the date of death of the Recipient, provided that the Recipient is employed by the Employer on the date of his/her death, or upon the termination of the Recipient's employment due to Disability. For purposes of the forgoing sentence "Disability" shall have the meaning set forth in Treasury Regulation 1.409A-3(i)(4)(i)(B) and shall be determined in accordance with such regulation.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3762

Samsung Bioepis Exhibit 1017, pg. 3762

4. Restrictions on Transfer. Unvested Shares may not be transferred or otherwise disposed of by the Recipient including by way of sale, assignment, transfer, pledge, hypothecation or otherwise, except as permitted by the Committee in its sole discretion.

5. Securities Laws Requirements. The Company shall not be obligated to transfer any Unvested Shares or other shares of Company Stock to the Recipient, if such transfer, in the opinion of counsel for the Company, would violate the Securities Act (or any other federal or state statutes having similar requirements as may be in effect at that time).

6. Invalid Transfers. No purported sale, assignment, mortgage, hypothecation, transfer, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any of the shares of Restricted Stock by any holder thereof in violation of the provisions of this Restricted Stock Agreement or the Certificate of Incorporation or the by-laws of the Company, shall be valid, and the Company will not transfer any of said shares of Restricted Stock on its books nor will any of said shares of Restricted Stock be entitled to vote, nor will any dividends be paid thereon, unless and until there has been full compliance with said provisions to the satisfaction of the Company. The foregoing restrictions are in addition to and not in lieu of any other remedies, legal or equitable, available to enforce said provisions.

7. Taxes. The Recipient shall promptly notify the Company of any election made pursuant to Section 83(b) of the Code. The Recipient shall pay to the Company promptly upon request, and in any event at the time the Recipient recognizes taxable income in respect to the shares of Restricted Stock (including if the Recipient makes an election under Section 83(b) of the Code in connection with such grant), an amount equal to the federal, state and/or local taxes the Company determines it is required to withhold under applicable tax laws with respect to the shares of Restricted Stock. The Recipient may satisfy the foregoing requirement by making a payment to the Company in cash or, with the consent of the Company, by authorizing the Company to withhold cash otherwise due to the Recipient. In addition, except where the Recipient makes an election under Section 83(b) of the Code, Recipient may elect to have any withholding obligation satisfied by surrendering to the Company a portion of the shares of Restricted Stock the vesting of which gives rise to the withholding obligation (but only to the extent of the minimum withholding required by law). Shares so surrendered by the Recipient shall be credited against any such withholding obligation at the Fair Market Value of such Shares on the date of such vesting (and the amount equal to the Fair Market Value of such Shares shall be remitted by the Company to the appropriate tax authorities). The Recipient understands that s/he (and not the Company) shall be responsible for any tax liability that may arise as a result of the transactions contemplated by this Restricted Stock Agreement.

THE RECIPIENT ACKNOWLEDGES THAT IT IS THE RECIPIENT'S SOLE RESPONSIBILITY AND NOT THE COMPANY'S TO FILE TIMELY THE ELECTION UNDER SECTION 83(b) OF THE CODE, IN THE EVENT THAT THE RECIPIENT DESIRES TO MAKE THE ELECTION.

8. Rights as a Stockholder. Pursuant to Section 8(e) of the Plan, the Company shall hold in escrow all dividends, if any, that are paid with respect to the Unvested Shares until all restrictions on such shares have lapsed. Pursuant to Section 8(f) of the Plan, the Recipient agrees (i) that the right to vote any Unvested Shares will be held by the Company and (ii) to execute an irrevocable proxy in favor of the Company in such form supplied by the Company.

9. Compliance with Law and Regulations. The award and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company may require, as a condition of the issuance and delivery of certificates evidencing Restricted Stock pursuant to the terms hereof, that the certificates bear such legends as set forth in the Plan, in addition to any other legends required under federal and state securities laws or as otherwise determined by the Committee. Except to the extent preempted by any federal law, this Restricted Stock Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3763

Samsung Bioepis Exhibit 1017, pg. 3763

10. Recipient Bound by Plan. The Recipient acknowledges receipt of a copy of the Plan and this Restricted Stock Agreement and agrees to be bound by all the terms and provisions thereof. The Plan is incorporated by reference, and any capitalized terms used but not defined herein shall have the same meanings as in the Plan. To the extent that this Restricted Stock Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Restricted Stock Agreement shall be deemed to be modified accordingly.

11. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Recipient, to: the Recipient at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Recipient has terminated service with the Company, to the last address for the Recipient indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 11.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3764

Samsung Bioepis Exhibit 1017, pg. 3764

Notice of Grant of Stock Options and Option Agreement for Performance Vesting Option Awards

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

[OPTIONEE NAME]
[OPTIONEE ADDRESS

Option Number: [ ]
Plan: 04
ID [ ]

Effective <data> (the Grant Date) you have been granted a Non-Qualified Stock Option to buy [ ] shares of Regeneron Pharmaceuticals, Inc. (the Company) stock at [$] per share.

The total option price of the shares granted is [$].

Stock options granted pursuant to this award will be eligible to vest on [ ]*. The number of stock options that will vest on that date will be determined based on the total number of points that are earned according to the table below during the period commencing on [ ] and ending on [ ]* (the Performance Measurement Period):

Total Points	Stock Options to Vest on [ ]*
[ ] or less	0
[ ]	[ ]
[ ]	[ ]
[ ]	[ ]
[ ]	[ ]
[ ] or more	[ ]

Total points in the table set forth above will be calculated based on the following criteria as achieved during the Performance Measurement Period:

[Description of performance criteria and allocation of points for achieving specific milestones]

For the avoidance of doubt, points may be earned upon achievement of the specified criteria by or on behalf of the Company or any subsidiary of the Company, including by any other entity pursuant to or in connection with any license or collaboration agreement under which such entity has rights to develop the Drug Candidate. For the further avoidance of doubt, the development of a Drug Candidate may earn points for [insert certain criteria].

Notwithstanding the foregoing, if [insert certain criteria] have not been achieved during the Performance Measurement Period, then the number of stock options from this award that will vest on [ ]* may not exceed [ ] unless otherwise determined by the Compensation Committee or there is an acceleration of this stock option award following a Change in Control pursuant to any employment agreement, change in control agreement or similar agreement in effect between the Grantee and the Company.

Notwithstanding anything to the contrary set forth herein, the Compensation Committee of the Board of Directors of the Company shall have the discretion to cause or accelerate the vesting of any or all of the stock options granted pursuant to this award.

The Compensation Committee of the Board of Directors of the Company shall have the authority in its sole discretion to determine whether the criteria required for earning the points in the table set forth above were achieved.

Notwithstanding anything to the contrary in the enclosed Option Agreement, if your employment with the Company ends before [ ]* as a result of your retirement, then stock options granted pursuant to this award will be eligible to vest on [ ]*, subject to the terms of this award, except that the number of stock options that will vest on that date will be equal to the product of (i) the total number of stock options that would have vested on that date absent your retirement based on the total number of points that are earned during the Performance Measurement Period in accordance with the table set forth above, and (ii) a fraction, where (A) the numerator equals the total number of full calendar months during which you were employed by the Company from [ ] through the effective date of your retirement, and (B) the denominator equals thirty-six (36).

The Non-Qualified Stock Option expires on [10 years from the Grant Date].

You and the Company agree that these options are granted under and governed by the terms and conditions of the Company's Amended and Restated 2000 Long-Term Incentive Plan and the enclosed Option Agreement, both of which are attached and made a part of this document.

---

* This date will be the last day of the Performance Measurement Period.

REGENERON PHARMACEUTICALS, INC.
OPTION AGREEMENT
PURSUANT TO THE
2000 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT, made as of the date on the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Stock Options* (the "Grantee");

WHEREAS, the Grantee is an employee of the Company and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the 2000 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's Common Stock ($.001 par value) (the "Common Stock") as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth here, the option to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share (the "Option") as shown on the *Notice of Grant of Stock Options*. [No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").]* [Notwithstanding the foregoing, the Option will not qualify as an Incentive Stock Option, among other events, (i) if the Grantee disposes of the Common Stock acquired pursuant to the Option at any time during the two year period following the date of this Agreement or the one year period following the date on which the Option is exercised, or (ii) if the Grantee is not employed by the Company or a subsidiary of the Company within the meaning of Section 424 of the Code (a "Subsidiary") at all times during the period beginning on the date of this Agreement and ending on the day three months before the date of exercise of the Option, or (iii) to the extent the aggregate fair market value (determined as of the time the Option is granted) of the stock subject to Incentive Stock Options which become exercisable for the first time in any calendar year exceeds $100,000. To the extent that the Option does not qualify as an Incentive Stock Option, it shall constitute a separate Non-Qualified Stock Option.]**

2. Vesting; Exercise. (a) The Option is exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Section 7(c)(1) & (2), the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. [In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having a Fair Market Value (as measured on the date of exercise) equal to the Option exercise price.]* The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.

(b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall be entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (collectively, the Company and all Subsidiaries shall be referred to herein as the "Employer" and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on the Full Vest Dates. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by the Employer and all unvested Options shall be forfeited at such time.

(c) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of termination of the Grantee's employment with the Employer if the Grantee's employment with the Employer is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Grantee for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Internal Revenue Code Section 4999 (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Grantee or, in the event the parties cannot agree, in the following order (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur, (2) any lump sum severance based on a multiple of base salary or bonus, (3) any other cash amounts payable to the Grantee, (4) any benefits valued as parachute payments, and (5) acceleration of vesting of any equity not covered by (1) above.

3. Option Term. (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as set forth in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement, or long-term disability, (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement, (C) one year after the termination if such termination is due to the Grantee's death or long-term disability, (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered) or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is by the Employer without Cause or by the Grantee for Good Reason.

(b) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Company and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer, including without limitation, repeated refusal to follow the reasonable directions of the Employer, knowing violation of law in the course of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, and intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours (other than any such failure resulting from his or her incapacity due to physical or mental illness); (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

(c) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by the Grantee within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Grantee to the Employer that Grantee intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Grantee's duties and responsibilities from that which exists immediately prior to a Change in Control (except in each case in connection with the termination of the Grantee's employment for Cause or as a result of the Grantee's death, or temporarily as a result of the Grantee's illness or other absence), or (2) the assignment to the Grantee of duties and responsibilities materially inconsistent with the position held by the Grantee; (B) any material breach by the Employer of any material provision of any written agreement with the Grantee or failure to timely pay any compensation obligation to the Grantee; (C) a reduction in the Grantee's annual base salary or target bonus opportunity (if any) from that which exists immediately prior to a Change in Control; or (D) if the Grantee is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Grantee's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* that defines "good reason" (or words of like import), as defined under such agreement or plan.

4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.

5. Rights of a Stockholder. The Grantee shall have no rights as a stockholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates for such shares. No adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor.

6. Compliance with Law and Regulations. This award and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates bear such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof. The Plan is incorporated herein by reference, and any capitalized term used but not defined herein shall have the same meaning as in the Plan. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment or service, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.

9. No Obligation to Continue Employment. This Agreement does not guarantee that the Employer will employ the Grantee for any specified time period, nor does it modify in any respect the Grantee's employment or compensation.

---

* For Non-Qualified Stock Option Awards.

** For Incentive Stock Option Awards.

Exhibit 10.11.7

SEVENTH AMENDMENT TO LEASE

THIS SEVENTH AMENDMENT TO LEASE (this "Seventh Amendment") is entered into as of this 22nd day of December, 2010 ("Execution Date"), by and between BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("Landlord"), and REGENERON PHARMACEUTICALS, INC., a New York corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant entered into that certain Lease dated as of December 21, 2006 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of October 24, 2007 (the "First Amendment"), that certain Second Amendment to Lease dated as of September 30, 2008 (the "Second Amendment"), that certain Third Amendment to Lease dated as of April 29, 2009 (the "Third Amendment"), that certain Fourth Amendment to Lease dated as of December 3, 2009 (the "Fourth Amendment"), that certain Fifth Amendment to Lease dated as of February 11, 2010 (the "Fifth Amendment"), and that certain Sixth Amendment to Lease dated as of June 4, 2010 (the "Sixth Amendment" and, collectively with the Original Lease and the First Amendment, Second Amendment, Third Amendment, Fourth Amendment, Fifth Amendment, and as the same may have been further amended, supplemented or otherwise modified from time to time, the "Lease"), whereby Tenant leases certain premises (the "Premises") from Landlord at 735, 745, 755, 765 and 777 Old Saw Mill River Road in Tarrytown, New York (collectively, the "Buildings", and each a "Building");

B. WHEREAS, pursuant to the Sixth Amendment, Tenant leased from Landlord and Landlord leased to Tenant certain space identified as the "765 Expansion Premises," consisting of two different phases; "Phase 1" and "Phase 2" (as such terms are defined in the Sixth Amendment), and as of the Execution Date hereof, Phase 2 has not yet been delivered to Tenant;

C. WHEREAS, pursuant to the Fifteenth Amendment of the Old Lease, Tenant leased from Landlord and Landlord leased to Tenant certain space, containing approximately five thousand two hundred thirty-three (5,233) square feet of Rentable Area and located on the C-Level of the 777 Building as shown on Exhibit D attached hereto (the "Old C-Level Storage Space");

D. WHEREAS, Tenant desires to lease from Landlord and Landlord desires to lease to Tenant the following space at the Project; (i) approximately five thousand one hundred twenty-one (5,121) square feet of Rentable Area on the mezzanine level of the 765 Building, as shown on Exhibit A attached hereto (the "765 Expansion Premises II"); (ii) approximately two thousand nine hundred two (2,902) square feet of Rentable Area (that is currently Common Area) located on the ground level of the 765 Building, as shown on Exhibit B attached hereto (the "Corridor Space"); and approximately five thousand ninety-five (5,095) square feet of Rentable Area on the C level of the 777 Building, as shown on Exhibit C attached hereto (the "New C-Level Storage Space");

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3772

Samsung Bioepis Exhibit 1017, pg. 3772

E. WHEREAS, Tenant desires to terminate the Lease with respect to the Swing Premises (as defined in the Fourth Amendment and consisting of approximately sixteen thousand seven hundred twenty-five (16,725) square feet of Rentable Area that is located on the Lobby level of the 777 Building); and

F. WHEREAS, Landlord and Tenant desire to modify and amend the Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Seventh Amendment, capitalized terms shall have the meanings ascribed to them in the Lease unless otherwise defined herein. The Lease, as amended by this Seventh Amendment, is referred to herein as the "Amended Lease."

2. Additions to Premises. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord the following space on the following terms:

a. the 765 Expansion Premises II, effective as of Landlord's delivery to Tenant of the same in the condition required under this Seventh Amendment including, without limitation, with the HVAC system located in the southeast corner of the 765 Expansion Premises being in good working condition and order. Landlord shall use commercially reasonable efforts to deliver the 765 Expansion Premises II on or before January 24, 2011. Landlord shall be responsible for demising the 765 Expansion Premises II at Landlord's sole cost and expense and shall deliver the 765 Expansion Premises II properly demised. The Term for the 765 Expansion Premises II shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, and (b) Tenant's termination option set forth in Section 7 below. Commencing as of the delivery of the 765 Expansion Premises II to Tenant and continuing through the Term, and subject to the provisions of Section 7 hereof, Tenant shall pay Landlord Basic Annual Rent for the 765 Expansion Premises II at an initial rate equal to Eighteen Dollars ($18.00) per square foot of Rentable Area, per year, in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the 765 Expansion Premises II shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011. In addition to Basic Annual Rent, commencing as of the delivery date of the 765 Expansion Premises II, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the 765 Expansion Premises II. For the avoidance of doubt (i) HVAC for the 765 Expansion Premises II shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the 765 Expansion Premises II shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (as of the commencement date for the 765 Expansion Premises II);

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3773

Samsung Bioepis Exhibit 1017, pg. 3773

b. the Corridor Space, effective as of Landlord's delivery to Tenant of the same in the condition required under this Seventh Amendment, and which shall be on the same date as the delivery of Phase 2 of the 765 Expansion Premises. Landlord shall use commercially reasonable efforts to deliver the Corridor Space on or before February 28, 2011. The Term for the Corridor Space shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, and (b) Tenant's termination option set forth in Section 7 below. Commencing as of the delivery of the Corridor Space to Tenant and continuing through the Term, and subject to the provisions of Section 7 hereof, Tenant shall pay Landlord Basic Annual Rent for the Corridor Space at an initial rate equal to Twenty-Four Dollars ($24) per square foot of Rentable Area, per year, in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the Corridor Space shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011. In addition to Basic Annual Rent, commencing as of the delivery date of the Corridor Space, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the Corridor Space. For the avoidance of doubt (i) HVAC for the Corridor Space shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the Corridor Space shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (as of the commencement date for the Corridor Space); and

c. the New C-Level Storage Space, effective as of Landlord's delivery to Tenant of the same in the condition required under this Seventh Amendment. Landlord shall use commercially reasonable efforts to deliver the New C-Level Storage Space on or before January 24, 2011. Landlord shall be responsible for demising the New C-Level Storage Space at Landlord's sole cost and expense and shall deliver the New C-Level Storage Space properly demised. The Term for the New C-Level Storage Space shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, and (b) Tenant's termination option set forth in Section 7 below. Commencing as of the delivery of the New C-Level Storage Space to Tenant and continuing through the Term, and subject to the provisions of Section 7 hereof, Tenant shall pay Landlord Basic Annual Rent for the New C-Level Storage Space at an initial rate equal to Five Dollars ($5) per square foot of Rentable Area, per year, in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the New C-Level Storage Space shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011. In addition to Basic Annual Rent, commencing as of the delivery date of the New C-Level Storage Space, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the New C-Level Storage Space. For the avoidance of doubt (i) HVAC for the New C-Level Storage Space shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the New C-Level Storage Space shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (as of the commencement date for the New C-Level Storage Space).

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3774

Samsung Bioepis Exhibit 1017, pg. 3774

3. Extension of Old C-Level Storage Space. The parties acknowledge that the term of the Old Lease expired on the Rent Commencement Date for the New Premises and that Tenant has been occupying the Old C-Level Storage Space on a month-to-month basis. Effective as of the date hereof, the Old C-Level Storage Space shall be included in the Amended Lease as a part of the Premises and the Old C-Level Storage Space shall be governed in all respects by the Amended Lease. The Term with respect to the Old C-Level Storage Space shall continue until the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, and (b) Tenant's termination option set forth in Section 7 below. Subject to the provisions of Section 7 hereof, Tenant shall pay Landlord Basic Annual Rent for the Old C-Level Storage Space at an initial rate equal to Five Dollars ($5.00) per square foot of Rentable Area, per year, in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the Old C-Level Storage Space shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011. In addition to Basic Annual Rent, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the Old C-Level Storage Space. For the avoidance of doubt (i) HVAC for the Old C-Level Storage Space shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the Old C-Level Storage Space shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (in each case, as of the applicable commencement date for each such portion of the Premises).

4. Tenant's Pro Rata Shares. From and after the delivery to Tenant of the 765 Expansion Premises II, the Corridor Space and the New C-Level Storage Space in the condition required hereunder, the Premises shall thereafter be deemed to include the premises so delivered and Tenant's Pro Rata Shares of the Building, Existing Project, New Project and Entire Project shall be incrementally adjusted as set forth in Exhibit E attached hereto. As of each such delivery date, the defined terms in Section 2.2 of the Lease shall be automatically amended to reflect the adjustments set forth in this Section 4. Rentable Area and Tenant's Pro Rata Shares are all subject to adjustment under the Amended Lease, including pursuant to Section 9.2.

5. Tenant Improvements. Landlord shall make available to Tenant a tenant improvement allowance equal to One Hundred Forty Nine Thousand Three Hundred Sixty Five Dollars ($149,365) (based on Fifteen Dollars ($15) per square foot of Rentable Area of the 765 Expansion Premises II and Twenty Five Dollars ($25) per square foot of Rentable Area of the Corridor Space)) (the "765 Allowance"). The 765 Allowance shall be disbursed in the same manner as the Base TI Allowance under the applicable provisions of Article 5 of the Lease, including, without limitation, the Disbursement Conditions, in order to finance improvements to the Premises in the 765 Building, consistent with the provisions of the Lease and the Permitted Use (such improvements, the "765 Improvements"). Tenant shall be responsible for performing and completing the 765 Improvements. Tenant shall pay Landlord a construction oversight fee of two and one-half percent (2.5%) of the total cost of the 765 Improvements, including, without limitation, the 765 Allowance to the extent disbursed to Tenant, which construction oversight fee may be paid out of the 765 Allowance.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3775

Samsung Bioepis Exhibit 1017, pg. 3775

6. Parking. The parties acknowledge that, in accordance with the Lease, Tenant shall be entitled to its pro rata share of unreserved parking spaces with respect to each portion of the Premises leased to Tenant hereunder.

7. Termination Options. Tenant shall be entitled to terminate the Lease with respect to (a) the entire 765 Expansion Premises II, effective as of January 1, 2017, (b) the Corridor Space, effective as of January 1, 2017 and (c) the New C-Level Storage Space and the Old C-Level Storage Space (the "C-Level Spaces"), on June 30, 2014, December 31, 2015 or December 31, 2016; provided that (x) Tenant provides Landlord with no less than nine (9) months' prior written notice and (y) concurrently with such notice, Tenant pays to Landlord an amount equal to (A) with respect to a termination of the 765 Expansion Premises II, Seventy-Three Thousand Nine Hundred Forty Seven and Fourteen and 24/100s Dollars ($73,947.24) (based on Fourteen and 44/100s Dollars ($14.44) per square foot of Rentable Area of the applicable portion of the Premises), (B) with respect to a termination the Corridor Space Fifty-Eight Thousand Forty and No/100s Dollars ($58,040.00) (based on Twenty and No/100 Dollars ($20.00) per square foot of Rentable Area of the applicable portion of the Premises) and (C) with respect to a termination of the C-Level Spaces, if terminated on June 30, 2014, Twenty Thousand Three Hundred Seventy-Eight Dollars ($20,378), if terminated on December 31, 2015, Seventeen Thousand Two Hundred Fourteen and 63/100s Dollars ($17,214.63) and if terminated on December 31, 2016, Fifteen Thousand One Hundred Eighty-Nine and 38/100s Dollars ($15,189.38).

If Tenant timely exercises its option to terminate the Lease with respect to one or more of the portions of the Premises set forth in this Section, then Tenant shall surrender the applicable Premises to Landlord on the applicable surrender date in the condition required by the Amended Lease for surrendering Premises upon the expiration. Notwithstanding anything to the Amended Lease to the contrary, if Tenant terminates the 765 Expansion Premises II in accordance with this Section 7, Tenant shall demise the 765 Expansion Premises II at its expense, such demising to be performed in accordance with Applicable Laws; provided, that the foregoing requirements shall in no event be deemed to require Tenant to perform any work to conform the 765 Expansion Premises II with Applicable Laws (other than the demising thereof), except as may be expressly required by the Amended Lease. Time is of the essence with respect to the exercise of the termination options granted in this Section.

8. Termination of Swing Premises. Effective upon the surrender of the Swing Premises in the condition required by the Amended Lease, the Lease shall terminate and shall be of no further force and effect with respect to the Swing Premises, except for those terms that expressly survive the expiration or earlier termination of the Amended Lease. Notwithstanding the foregoing, Tenant shall not be responsible for payment of Base Rent or Tenant's Pro Rata Share of Operating Expenses with respect to the Swing Premises effective as of the mutual execution and delivery of this Seventh Amendment; provided, however, Tenant shall surrender the Swing Premises in the required condition on or before the date that is sixty (60) days after the delivery of the New C-Level Space. If Tenant shall fail to timely surrender the Swing Premises in the requisite condition, Tenant shall become a tenant at sufferance of only the entire Swing Premises subject to the terms and conditions of the Amended Lease, except that the monthly rent beginning the first day after the expiration of such sixty (60) day period shall be recalculated to equal one hundred fifty percent (150%) of the Rent rates in effect immediately prior to the Execution Date hereof with respect of the Swing Premises.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3776

Samsung Bioepis Exhibit 1017, pg. 3776

9. Lease Extension Options. From and after the Execution Date, the first paragraph of Article 44 of the Lease is hereby deleted and replaced with the following:

> 44. Option to Extend Term. Tenant shall have three (3) options (each, an "Option") to extend the Term of this Lease (and, in each case, the Term Expiration Date) by five (5) years, in each case on the same terms and conditions as this Lease, except as provided below. If Tenant desires to exercise any Option, Tenant must do so by giving Landlord written notice of such exercise at least one (1) year before the Term would otherwise expire. Tenant may exercise its Option to extend the Term only as to any one or more of the following: (a) the entire Retained Premises plus the Corridor Space, (b) the entire New Whole Building Premises, (c) the entire New Multiple Tenant Building Premises, (d) the Modified Additional Premises, (e) the Swap Premises, (f) each full floor of the 755 Premises, (h) the 765 Expansion Premises, (i) the 765 Expansion Premises II, (j) C-Level Storage Spaces. If Tenant fails to exercise an Option with respect to less than all of the Premises and the time to do so has lapsed (or if a Retained Premises Early Termination or a termination pursuant to a Swap Premises Termination Option has occurred), then Tenant shall no longer have an Option with respect to those portions of the Premises for which it failed to exercise an Option. Tenant's Options for the remaining Premises shall remain in full force and effect.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3777

Samsung Bioepis Exhibit 1017, pg. 3777

10. Condition of Premises. Except as otherwise provided herein (including without limitation Section 2 hereof), Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the 765 Expansion Premises II, the Corridor Space, the Old C-Level Storage Space, or the New C-Level Storage Space with respect to the suitability of the same for the conduct of Tenant's business. Tenant acknowledges that (a) it is generally familiar with the condition of the 765 Expansion Premises II, the Corridor Space, the Old C-Level Storage Space, and the New C-Level Storage Space, notwithstanding anything contained in the Amended Lease to the contrary, agrees to take the same in its condition "as is" as of the applicable delivery date, and with respect to the Old C-Level Storage Space, as of the Execution Date hereof. Tenant's taking of possession of the 765 Expansion Premises II, the Corridor Space and the new C-Level Storage Space shall, except as otherwise agreed to in writing by Landlord and Tenant, conclusively establish that the same were at such time in good, sanitary and satisfactory condition and repair. Notwithstanding the foregoing, Landlord represents and warrants that, with the exception of the HVAC system located in the southeast corner of the 765 Expansion Premises II (which Landlord acknowledges is currently not in good working condition), the Building Systems in the 765 Expansion Premises II, the Corridor Space, the Old C-Level Storage Space, and the New C-Level Storage Space are, and will be (including the HVAC system located in the southeast corner of the 765 Expansion Premises II), in good working condition and that the same are adequately serviced by Utilities and other base building services.

11. Hazardous Materials. From and after the Execution Date, the second to last sentence of Section 40.1 of the Lease shall be deleted and replaced in its entirety with the following:

> Landlord acknowledges that Tenant shall not be responsible for environmental conditions or contamination now or hereafter existing on, under or in the Entire Project, in the New Whole Building, in the New Multiple Tenant Building, or in the Premises (as the Premises may be modified from time to time) caused by Landlord or tenants other than Tenant or by third parties in the Entire Project prior to the Execution Date or after such date, or for environmental conditions or contamination coming from off-site so long as Tenant, Tenant's Affiliates, its permitted sublessees or its agents did not cause or contribute to such environmental conditions or contamination.

12. Broker. Each of Landlord and Tenant represents and warrants to the other that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Seventh Amendment, other than Studley ("Broker") on behalf of Tenant, and each agrees to indemnify, defend and hold the other harmless from any and all cost or liability for compensation claimed by any such broker or agent, other than Broker, employed or engaged by it or claiming to have been employed or engaged by it. Broker is entitled to a leasing commission in connection with this Seventh Amendment, and Landlord shall pay such commission to Broker pursuant to a separate agreement between Landlord and Broker.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3778

Samsung Bioepis Exhibit 1017, pg. 3778

13. No Default; Authority; Non-Contravention. Each of Landlord and Tenant represents, warrants and covenants that, to the best of its respective knowledge, neither Landlord nor Tenant is in default of any of its respective obligations under the Lease and no event has occurred that, with the passage of time or the giving of notice (or both), would constitute a default by either Landlord or Tenant thereunder. Each of Landlord and Tenant further represents, warrants and covenants that it has the full power and authority to execute, deliver and comply with the terms of this Seventh Amendment, and doing so will not conflict with or result in the violation of or default under any provision of any agreement or other instrument to which it is a party.

14. Effect of Amendment. Except as modified by this Seventh Amendment, the Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. The covenants, agreements, terms, provisions and conditions contained in this Seventh Amendment shall bind and inure to the benefit of the parties hereto and their respective successors and, except as otherwise provided in the Lease, their respective assigns. In the event of any conflict between the terms contained in this Seventh Amendment and the Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties. From and after the date hereof, the term "Lease" as used in the Lease shall mean the Lease, as modified by this Seventh Amendment.

15. Miscellaneous. This Seventh Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Seventh Amendment are included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference.

16. Counterparts. This Seventh Amendment may be executed in one or more counterparts that, when taken together, shall constitute one original.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3779

Samsung Bioepis Exhibit 1017, pg. 3779

IN WITNESS WHEREOF, Landlord and Tenant have hereunto set their hands as of the date and year first above written, and acknowledge that they possess the requisite authority to enter into this transaction and to execute this Seventh Amendment to Lease.

LANDLORD:

BMR-LANDMARK AT EASTVIEW LLC,
a Delaware limited liability company

By: /s/ Kevin M. Simonsen
Name: Kevin M. Simonsen
Title: VP, Real Estate Counsel

TENANT:

REGENERON PHARMACEUTICALS, INC.,
a New York corporation

By: /s/ Murray A; Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance & Administration and Chief Financial Officer

EXHIBIT A

765 EXPANSION PREMISES II

[IMAGE]

EXHIBIT B

CORRIDOR SPACE

[IMAGE]

EXHIBIT C

NEW C-LEVEL STORAGE SPACE

[IMAGE]

EXHIBIT D

OLD C-LEVEL STORAGE SPACE

[IMAGE]

EXHIBIT E

Definition or Provision	**Means the Following:**	**Square Feet of Rentable Area**	**Tenant's Pro Rata Share of Applicable Building**	**Tenant's Pro Rata Share of Existing Project (827,790)**	**Tenant's Pro Rata Share of the Entire Project (1,188,310)**
Portion of added "Premises" and corresponding Rentable Area	765 Expansion Premises II	5,121	2.46 %	.62 %	.43%
	Corridor Space	2,902	1.40 %	.35 %	.24%
	Old C-Level Storage Space	5,233	1.43 %	.63 %	.44%
	New C-Level Storage Space	5,095	1.39 %	.62 %	.43%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-61132, 333-97375, 333-119257, 333-151941, and 333-169569) and on Form S-3 (No. 333-169786) of Regeneron Pharmaceuticals, Inc., of our report dated February 17, 2011 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

New York, New York
February 17, 2011

Exhibit 31.1

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting: and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 17, 2011

By: /s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 31.2

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting: and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 17, 2011

By: /s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and Assistant
Secretary

Exhibit 32

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
February 17, 2011

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
February 17, 2011

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 5/8/2006

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2006

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.
Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of April 30, 2006:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,307,561
Common Stock, $0.001 par value	54,643,326

REGENERON PHARMACEUTICALS, INC.
Table of Contents
March 31, 2006

		Page Numbers
PART I	**FINANCIAL INFORMATION**	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at March 31, 2006 and December 31, 2005	3
	Condensed statements of operations (unaudited) for the three months ended March 31, 2006 and 2005	4
	Condensed statement of stockholders' equity (unaudited) for the three months ended March 31, 2006	5
	Condensed statements of cash flows (unaudited) for the three months ended March 31, 2006 and 2005	6
	Notes to condensed financial statements (unaudited)	7-16
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	17-30
Item 3	Quantitative & Qualitative Disclosure About Market Risk	30-31
Item 4	Controls and Procedures	31
PART II	**OTHER INFORMATION**	
Item 1	Legal Proceedings	31
Item 1A	Risk Factors	31-46
Item 6	Exhibits	46
SIGNATURE PAGE		47

EX-12.1:STMNT RE:COMPUTATION OF RATIO OF EARNINGS TO COMBINED FIXED CHARGES
EX-31.1: CERTIFICATION
EX-31.2: CERTIFICATION
EX-32: CERTIFICATION

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT MARCH 31, 2006 AND DECEMBER 31, 2005 (Unaudited)
(In thousands, except share data)

	March 31, 2006	December 31, 2005
ASSETS		
Current assets		
Cash and cash equivalents	$ 182,332	$ 184,508
Marketable securities	120,061	114,037
Accounts receivable	11,010	36,521
Prepaid expenses and other current assets	2,990	3,422
Inventory	3,254	2,904
Total current assets	319,647	341,392
Marketable securities	21,836	18,109
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	57,421	60,535
Other assets	3,185	3,465
Total assets	$ 402,089	$ 423,501
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 18,383	$ 23,337
Deferred revenue, current portion	15,284	17,020
Total current liabilities	33,667	40,357
Deferred revenue	66,099	69,142
Notes payable	200,000	200,000
Total liabilities	299,766	309,499
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,307,561 in 2006 and 2,347,073 in 2005	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 54,614,557 in 2006 and 54,092,268 in 2005	55	54
Additional paid-in capital	708,297	700,011
Unearned compensation		(315)
Accumulated deficit	(605,660)	(585,280)
Accumulated other comprehensive loss	(371)	(470)
Total stockholders' equity	102,323	114,002
Total liabilities and stockholders' equity	$ 402,089	$ 423,501

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3793

Samsung Bioepis Exhibit 1017, pg. 3793

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended March 31, 2006	2005
Revenues		
Contract research and development	$ 14,587	$ 13,502
Contract manufacturing	3,632	2,707
	18,219	16,209
Expenses		
Research and development	32,084	35,912
Contract manufacturing	1,852	2,491
General and administrative	5,946	6,146
	39,882	44,549
Loss from operations	(21,663)	(28,340)
Other income (expense)		
Other contract income		25,000
Investment income	3,481	2,230
Interest expense	(3,011)	(3,013)
	470	24,217
Net loss before cumulative effect of a change in accounting principle	(21,193)	(4,123)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")	813	
Net loss	($ 20,380)	($ 4,123)
Net loss per share amounts, basic and diluted:		
Net loss before cumulative effect of a change in accounting principle	($ 0.37)	($ 0.07)
Cumulative effect of adopting SFAS 123R	0.01	
Net loss	($ 0.36)	($ 0.07)
Weighted average shares outstanding, basic and diluted	56,727	55,815

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3794

Samsung Bioepis Exhibit 1017, pg. 3794

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
For the three months ended March 31, 2006
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount						
Balance, December 2005	2,347	$2	54,092	$54	$700,011	$(315)	$(585,280)	$(470)	$114,002	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			364	1	3,415				3,416	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contributio			121		1,884				1,884	
Conversion of Class A Stock to Common Stock	(40)		40							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(2)							
Stock-based compensation expense					4,115				4,115	
Adjustment to reduce unearned compensati upon adoption of SFAS 123R					(315)	315				
Cumulative effect of adopting SFAS 123R					(813)				(813)	
Net loss							(20,380)		(20,380)	$(20,380)
Change in net unrealized loss on marketable securities								99	99	99
Balance, March 31, 2006	2,307	$2	54,615	$55	$708,297	—	$(605,660)	$(371)	$102,323	$(20,281)

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3795

Samsung Bioepis Exhibit 1017, pg. 3795

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Three months ended March 31, 2006	2005
Cash flows from operating activities		
Net loss	$ (20,380)	$ (4,123)
Adjustments to reconcile net loss to net cash provided by operating activities		
Depreciation and amortization	3,798	3,858
Non-cash compensation expense	4,079	5,881
Cumulative effect of a change in accounting principle	(813)	
Changes in assets and liabilities		
Decrease in accounts receivable	25,511	32,731
Decrease (increase) in prepaid expenses and other assets	1,023	(40)
(Increase) decrease in inventory	(92)	527
Decrease in deferred revenue	(4,779)	(4,653)
Decrease in accounts payable, accrued expenses, and other liabilities	(3,069)	(1,049)
Total adjustments	25,658	37,255
Net cash provided by operating activities	5,278	33,132
Cash flows from investing activities		
Purchases of marketable securities	(74,541)	(35,601)
Sales or maturities of marketable securities	64,317	55,385
Capital expenditures	(646)	(1,359)
Net cash (used in) provided by investing activities	(10,870)	18,425
Cash flows from financing activities		
Net proceeds from the issuance of stock	3,416	1,030
Net cash provided by financing activities	3,416	1,030
Net (decrease) increase in cash and cash equivalents	(2,176)	52,587
Cash and cash equivalents at beginning of period	184,508	95,229
Cash and cash equivalents at end of period	$ 182,332	$ 147,816

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3797

Samsung Bioepis Exhibit 1017, pg. 3797

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2005 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. For the three months ended March 31, 2006 and 2005, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended March 31,	
	2006	2005
Net loss (Numerator)	($ 20,380)	($ 4,123)
Weighted-average shares, in thousands (Denominator)	56,727	55,815
Basic and diluted net loss per share	($ 0.36)	($ 0.07)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the March 31, 2006 and 2005 diluted per share amounts because their effect would have been antidilutive, include the following:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3798

Samsung Bioepis Exhibit 1017, pg. 3798

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended March 31,	
	2006	2005
Stock Options:		
Weighted average number, in thousands	14,401	13,476
Weighted average exercise price	$ 14.27	$ 14.73
Restricted Stock:		
Weighted average number, in thousands	54	213
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

3. Stock-based Employee Compensation

Adoption of Statement of Financial Accounting Standards Nos. 123 and 123R

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation- Transition and Disclosure*. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by $813 and is

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3799

Samsung Bioepis Exhibit 1017, pg. 3799

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

included in the Company's operating results for the first quarter of 2006 as a cumulative-effect adjustment of a change in accounting principle.

Long-Term Incentive Plans

The Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan"), as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, certain shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. The 1990 Incentive Plan, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. The Company has issued Incentive Stock Options ("ISOs") and Nonqualified Stock Options, and shares of Restricted Stock from the 1990 and 2000 Incentive Plans. The terms of the awards are determined by the Compensation Committee of the board of directors; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the ISO is granted and no ISO is exercisable more than ten years after the date of grant. As of March 31, 2006, there were 6,490,581 shares available for future grants under the 2000 Incentive Plan.

a. Stock Options

At March 31, 2006, there were 14,199,554 stock options outstanding with exercise prices ranging from $4.83 to $51.56. Options granted to employees generally vest annually on a pro rata basis over a four to five year period beginning one year from the date of grant. Certain performance-based options granted to the Company's executive vice president and senior vice presidents vest if both (i) the Company's products have achieved defined sales targets and (ii) the option recipient has remained employed by the Company for at least three years from the date of grant. Options granted to members of the Company's board of directors vest annually on a pro rata basis over three years beginning one year from the date of grant. A summary of the Company's stock option activity for the three months ended March 31, 2006 is presented in the following table:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3800

Samsung Bioepis Exhibit 1017, pg. 3800

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Intrinsic Value (in thousands)
Stock options outstanding at January 1, 2006	14,719,492		$ 14.23	
Stock options granted	138,700		$ 15.99	
Stock options exercised	(393,526)		$ 9.93	
Stock options forfeited	(152,016)		$ 10.60	
Stock options expired	(113,096)		$ 26.52	
Stock options outstanding at March 31, 2006	14,199,554	6.8	$ 14.31	$ 67,940
Stock options vested and exercisable	7,226,662	5.3	$ 17.68	$ 27,579

The total intrinsic value of stock options exercised during the first quarter of 2006 and 2005 was $2,592 and $200, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

For the three months ended March 31, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") totaled $3,931 and $5,541, respectively. Stock Option Expense recognized in operating expenses for the three months ended March 31, 2006 and 2005 was $3,895 and $5,379, respectively, and $36 and $162, respectively, was capitalized into inventory. As of March 31, 2006, there was $27,331 of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years. In addition, there are 723,092 options which are unvested as of March 31, 2006 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals $2,688 and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Fair Value Assumptions:

The fair value of each option granted during the three months ended March 31, 2006 and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and board directors are expected to hold their options prior to exercise

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3801

Samsung Bioepis Exhibit 1017, pg. 3801

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

(expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The weighted-average fair value of the options granted during the three months ended March 31, 2006 and 2005 was $11.28 and $5.86 per option, respectively. The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants.

	Three months ended March 31,	
	2006	2005
Expected volatility	69 %	75 %
Expected lives from grant date	7.7 years	6.2 years
Expected dividend yield	0 %	0 %
Risk-free interest rate	4.67 %	3.96 %

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the three months ended March 31, 2006 is presented in the following table:

	Number in Shares	Weighted Average Grant Date Fair Value
Restricted stock outstanding as of January 1, 2006	95,188	$ 11.16
Restricted stock released	(45,040)	$ 13.00
Restricted stock forfeited	(1,703)	$ 9.74
Restricted stock outstanding as of March 31, 2006	48,445	$ 9.49

In accordance with generally accepted accounting principles, the Company recorded unearned compensation in Stockholders' Equity related to these Restricted Stock awards. The amount was based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restrictions lapse, which is approximately two years for grants issued in 2003 and 18 months for grants issued in 2004. No Restricted Stock awards were granted in 2005 or during the three months ended March 31, 2006. For the three months ended March 31, 2006 and 2005, the Company recognized compensation expense related to Restricted Stock awards of $184 and $502, respectively. Unrecognized compensation cost at March

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3802

Samsung Bioepis Exhibit 1017, pg. 3802

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

31, 2006 related to outstanding Restricted Stock awards totaled $115, which the Company expects to recognize over a weighted-average period of approximately 2.5 months.

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2006 and December 31, 2005 are $233 and $234, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2005 and December 31, 2004 are $827 and $550, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2005 and 2004 are $1,884 and $632, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2006 and 2005, the Company contributed 120,960 and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at March 31, 2006 and December 31, 2005 are $656 and $1,228, respectively, of accrued interest income. Included in marketable securities at March 31, 2005 and December 31, 2004 are $1,760 and $2,601, respectively, of accrued interest income.

5. Severance Costs

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the expected completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005, with the remainder planned for 2006 following the completion of the Company's contract manufacturing activities for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and are being expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. The Company estimates that total costs associated with the 2005 and planned 2006 workforce reductions will approximate $2.6 million, including $0.2 million of non-cash expenses in 2005.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3803

Samsung Bioepis Exhibit 1017, pg. 3803

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

Severance costs associated with the workforce reduction plan that were charged to expense in the first quarter of 2006 consist of the following:

	Accrued liability at December 31, 2005	Three months ended March 31, 2006		Accrued liability at March 31, 2006
		Costs charged to expense	Costs paid or settled in 2006	
Employee severance, payroll taxes, and benefits	$ 907	$ 159	$ 641	$ 425
Other severance costs	176	14	190	—
Total	$ 1,083	$ 173	$ 831	$ 425

These severance costs are included in the Company's Statement of Operations for the three months ended March 31, 2006 as follows:

	Research & development	General & administrative
Employee severance, payroll taxes, and benefits	$ 161	($ 2)
Other severance costs	14	—
Total	$ 175	($ 2)

For segment reporting purposes (see Note 10), all severance-related expenses are included in the Research & Development segment.

6. Accounts Receivable

Accounts receivable as of March 31, 2006 and December 31, 2005 consist of the following:

	March 31, 2006	December 31, 2005
Receivable from the sanofi-aventis Group	$ 10,972	$ 36,412
Receivable from Merck & Co., Inc.	38	27
Other	—	82
	$ 11,010	$ 36,521

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3804

Samsung Bioepis Exhibit 1017, pg. 3804

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

7. Inventories

Inventories consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which will expire in October 2006.

Inventories as of March 31, 2006 and December 31, 2005 consist of the following:

	March 31, 2006	December 31, 2005
Raw materials	$ 279	$ 278
Work-in-process	785	1,423
Finished products	2,190	1,203
	$ 3,254	$ 2,904

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2006 and December 31, 2005 consist of the following:

	March 31, 2006	December 31, 2005
Accounts payable	$ 3,758	$ 4,203
Accrued payroll and related costs	3,638	10,713
Accrued clinical trial expense	3,723	3,081
Accrued expenses, other	2,222	3,048
Interest payable on convertible notes	5,042	2,292
	$ 18,383	$ 23,337

9. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three months ended March 31, 2006 and 2005, the components of comprehensive loss are:

	Three months ended March 31,	
	2006	2005
Net loss	($ 20,380)	($ 4,123)
Change in net unrealized gain (loss) on marketable securities	99	(341)
Total comprehensive loss	($ 20,281)	($ 4,464)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3805

Samsung Bioepis Exhibit 1017, pg. 3805

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

10. Segment Information

The Company's operations are managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and (ii) the supply of research materials based on Regeneron-developed proprietary technology.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. The Company produces an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which will expire in October 2006.

The table below presents information about reported segments for the three months ended March 31, 2006 and 2005.

	Three months ended March 31, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 14,587	$ 3,632	—	$ 18,219
Depreciation and amortization	3,537	—(1)	$ 261	3,798
Non-cash compensation expense	3,984	95	(813)(2)	3,266
Interest expense	—	—	3,011	3,011
Net (loss) income	(23,443)	1,780	1,283 (3)	(20,380)
Capital expenditures	645	—	—	645
Total assets	67,159	4,526	330,404 (4)	402,089

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3806

Samsung Bioepis Exhibit 1017, pg. 3806

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended March 31, 2005			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 13,502	$ 2,707	—	$ 16,209
Depreciation and amortization	3,597	—(1)	$ 261	3,858
Non-cash compensation expense	5,881	—	—	5,881
Other contract income	25,000	—	—	25,000
Interest expense	—	—	3,013	3,013
Net (loss) income	(3,556)	216	(783)(3)	(4,123)
Capital expenditures	1,637	—	—	1,637
Total assets	77,527	4,986	387,779 (4)	470,292

(1) Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

(2) Represents the cumulative effect of adopting SFAS 123R (see Note 3).

(3) Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the three months ended March 31, 2006, also includes the cumulative effect of adopting SFAS 123R.

(4) Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3807

Samsung Bioepis Exhibit 1017, pg. 3807

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: VEGF Trap in oncology, VEGF Trap eye formulation (VEGF Trap-Eye) in eye diseases using intraocular delivery, and IL-1 Trap in various inflammatory indications. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing Traps and Human Monoclonal Antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse pipeline of product candidates that we believe has the potential to address a variety of serious medical conditions. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our Traps, Human Monoclonal Antibody (VelocImmune™), and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3808

Samsung Bioepis Exhibit 1017, pg. 3808

Clinical Programs:

Below is a summary of the clinical status of our clinical candidates as of March 31, 2006:

1. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regnlator of vascular permeability and leakage. The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis, as described below. In September 2005, we and sanofi-aventis announced plans to expand our joint development program.

In the first quarter of 2006, we and sanofi-aventis initiated our phase 2 single-agent program for the VEGF Trap in cancer. Patient enrollment is underway in non-small cell adenocarcinoma and two additional safety/efficacy studies in advanced ovarian cancer and symptomatic malignant ascites are planned to begin shortly. In 2004, the United States Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for the treatment of symptomatic malignant ascites.

The companies also plan to conduct three efficacy/safety trials using the VEGF Trap in combination with standard chemotherapy regimens, the first of which is planned to begin in the second half of 2006, assuming successful completion of initial safety and tolerability studies. Currently there are five safety and tolerability studies underway for the VEGF Trap in combination with standard chemotherapy regimens in a variety of cancer types. The companies are also finalizing plans with the National Cancer Institute (NCI) Cancer Therapeutics Evaluation Program to commence at least ten additional cancer trials in 2006.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to support the tumor. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has been shown to provide therapeutic benefits. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (now a member of the sanofi-aventis Group) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3809

Samsung Bioepis Exhibit 1017, pg. 3809

exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to $400.0 million in milestone payments upon receipt of specified marketing approvals, including up to $360.0 million in milestone payments related to up to eight VEGF Trap oncology and other indications in the United States or the European Union.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obliged to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. (See "The sanofi-aventis Group Agreement" below.)

2. VEGF Trap — Eye Diseases

We are developing the VEGF Trap-Eye for the treatment of certain eye diseases. This product candidate has been purified and formulated in concentrations suitable for direct injection into the eye. We retain the exclusive right to develop and commercialize the VEGF Trap-Eye for the treatment of eye diseases utilizing local (intravitreal) delivery to the eye. We recently announced that we have initiated a phase 2 trial of the VEGF Trap-Eye delivered intravitreally in patients with the neovascular form of age-related macular degeneration (wet AMD).

At the May 2006 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO), we reported positive preliminary results from a phase 1 trial of the VEGF Trap-Eye in patients with the neovascular form of wet AMD. A total of 21 patients received a single dose of VEGF Trap-Eye at doses ranging of 0.05, 0.15, 0.5, 1, 2, and 4 milligrams (mg) intravitreally (direct injection into the eye) and were evaluated for six weeks to measure the durability of effects and provide guidance for dosing regimens to be used in future trials. All dose levels were generally well tolerated, and a maximum tolerated dose was not reached in the study. Patients receiving the VEGF Trap-Eye demonstrated large, rapid, and sustained (at least six weeks) reductions in retinal thickness, a clinical measure of disease activity in wet AMD as measured by ocular coherence tomography (OCT). As measured by the OCT reading center (posterior pole OCT scans), the median excess retinal thickness was 194 microns at baseline and 60 microns at 6 weeks. As measured by the computerized Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline and 27 microns at 6 weeks.

Of the 20 patients evaluable for efficacy, 95 percent had stabilization or improvement in visual acuity, defined as ≤ 15 letter loss on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. Patients were also evaluated for best-corrected visual acuity (BCVA), the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3810

Samsung Bioepis Exhibit 1017, pg. 3810

best acuity a person can achieve with glasses. BCVA for all patients in the study increased by a mean of 4.8 letters at 6 weeks. In the two highest dose groups (2 mg and 4 mg), the mean improvement in BCVA was 13.5 letters, with three of six patients showing an improvement in BCVA of 15 or more letters.

Based on the preliminary phase 1 results in wet AMD, we initiated a 150 patient, 12 week, phase 2 trial of the VEGF Trap in wet AMD. The trial is designed to evaluate treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens, as well as safety and efficacy. We plan to conduct an initial evaluation of phase 2 study results after all patients have completed 12 weeks of treatment, which is expected to be prior to the end of 2006. Subject to a review of the initial phase 2 study results, we plan to initiate a phase 3 trial of the VEGF Trap in wet AMD in early 2007.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and Diabetic Retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) has been approved to treat patients with this condition.

Wet AMD and Diabetic Retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. It is estimated that in the U.S. 6% of individuals aged 65-74 and 20% of those older than 75 are affected with wet AMD. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as Diabetic Macular Edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

3. IL-1 Trap — Inflammatory Diseases

The IL-1 Trap is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors.

We are evaluating the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called *CIAS*1-Associated Periodic Syndrome (CAPS) and diseases associated with inflammation. These include Systemic Juvenile Idiopathic Arthritis (SJIA) and certain inflammatory vascular diseases.

In April 2006, we completed enrollment of the pivotal study of the IL-1 Trap in patients with CAPS. The six-month, placebo-controlled efficacy phase is expected to be completed by the end of 2006. This phase will be followed by a six-month open-label extension phase. In December 2004, the FDA granted orphan drug status to the IL-1 Trap for the treatment of CAPS. In April 2005, the FDA also granted orphan drug status to the IL-1 Trap for the treatment of SJIA.

An IL-1 receptor antagonist, Kineret® (Amgen Inc.), has been approved by the FDA for the treatment of rheumatoid arthritis. It has been publicly reported that in small trials Kineret

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3811

Samsung Bioepis Exhibit 1017, pg. 3811

appears to reduce the symptoms in CAPS patients and SJIA patients, which supports the role of IL-1 in these diseases. CAPS includes rare genetic disorders, such as Familial Cold Auto-Inflammatory Syndrome (FCAS), Muckle Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disorder (NOMID), which affect a small group of people. Patients with these disorders develop fever, joint aches, headaches, and rashes. In certain indications, these symptoms can be extremely serious. There are no currently approved therapies for CAPS. SJIA is a severe inflammatory disorder which may be debilitating or fatal. It is estimated that there are between 5,000 and 10,000 children with SJIA in the United States.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our IL-1 Trap currently in clinical development.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2006, we had a cumulative loss of $605.7 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and IL-1 Trap; advance new product candidates into clinical development from our existing research programs; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3812

Samsung Bioepis Exhibit 1017, pg. 3812

substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events and plans in 2006 are as follows:

Product candidate	2006 Events	2006 Plans
VEGF Trap — Oncology	• Initiated phase 2 study of the VEGF Trap as a single agent in non-small cell lung adenocarcinoma • Initiated two safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens	• Initiate two efficacy/safety studies of the VEGF Trap as a single agent in advanced ovarian cancer and symptomatic malignant ascites • Initiate an efficacy/safety study of the VEGF Trap in combination with a standard chemotherapy regimen in cancer patients • Design two additional efficacy/safety trials of the VEGF Trap in combination with standard chemotherapy regimens in different cancer indications • Finalize plans with the NCI to sponsor at least ten exploratory efficacy/safety studies evaluating the VEGF Trap in a variety of cancer types
VEGF Trap-Eye	• Reported positive preliminary results from phase 1 trial in wet AMD utilizing intravitreal injections in 21 patients up to a top dose of 4 mg • Initiated a phase 2 trial in wet AMD utilizing intravitreal injections	• Report preliminary results of a phase 2 trial in wet AMD utilizing intravitreal injections
IL-1 Trap	• Completed enrollment of pivotal trial of IL-1 Trap in CAPS	• Complete efficacy portion of pivotal study in CAPS Evaluate the • IL-1 Trap for SJIA

Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation- Transition and Disclosure*. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3813

Samsung Bioepis Exhibit 1017, pg. 3813

expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, Share-Based Payment, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by $0.8 million and is included in our operating results for the first quarter of 2006 as a cumulative-effect adjustment of a change in accounting principle.

For the three months ended March 31, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") totaled $3.9 million and $5.6 million, respectively, of which $3.9 million and $5.4 million was recognized in operating expenses. Stock Option Expense of $0.2 million was capitalized into inventory in the first quarter of 2005. As of March 31, 2006, there was $27.3 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.8 years. In addition, there are 723,092 options which are unvested as of March 31, 2006 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals $2.7 million and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3814

Samsung Bioepis Exhibit 1017, pg. 3814

values of the assumptions we used in computing the fair value of option grants during the three months ended March 31, 2006 and 2005:

	Three months ended March 31,	
	2006	2005
Expected volatility	69 %	75 %
Expected lives from grant date	7.7 years	6.2 years
Expected dividend yield	0 %	0 %
Risk-free interest rate	4.67 %	3.96 %

Changes in any of these estimates may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

Results of Operations

Three Months Ended March 31, 2006 and 2005

Net Income (Loss):

Regeneron reported a net loss of $20.4 million, or $0.36 per share (basic and diluted), for the first quarter of 2006 compared to a net loss of $4.1 million, or $0.07 per share (basic and diluted), for the first quarter of 2005. Results for the first quarter of 2005 included a $25.0 million one-time, non-recurring payment from sanofi-aventis, which was recognized as other contract income, in connection with the January 2005 amendment to our collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye.

Revenues:

Revenues for the three months ended March 31, 2006 and 2005 consist of the following:

(In millions)	2006	2005	Increase (Decrease)
Contract research & development revenue			
The sanofi-aventis Group	$ 13.9	$ 9.8	$ 4.1
The Procter & Gamble Company	—	3.1	(3.1)
Other	0.7	0.6	0.1
Total contract research & development revenue	14.6	13.5	1.1
Contract manufacturing revenue	3.6	2.7	0.9
Total revenue	$ 18.2	$ 16.2	$ 2.0

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to $105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3815

Samsung Bioepis Exhibit 1017, pg. 3815

period over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104).

Sanofi-aventis Contract Research & Development Revenue

(In millions)	Three months ended March 31, 2006	2005
Regeneron expense reimbursement	$ 10.8	$ 7.4
Recognition of deferred revenue related to up-front payments	3.1	2.4
Total	$ 13.9	$ 9.8

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses increased in the first quarter of 2006 from the same period in 2005, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in the first quarter of 2006 from the same period in 2005, due to our January 2006 receipt of a $25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan. As of March 31, 2006, $78.3 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract research and development revenue earned from Procter & Gamble decreased in the first quarter of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

Contract manufacturing revenue relates to our long-term agreement with Merck, which expires in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Contract manufacturing revenue increased in the first quarter of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Revenue and the related manufacturing expense are recognized as product is shipped, after acceptance by Merck. Included in contract manufacturing revenue in both the first three months of 2006 and 2005 were $0.4 million and $0.3 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. As of March 31, 2006, the remaining deferred balance of Merck's capital improvement reimbursements totaled $0.9 million, which will be recognized as revenue as product is shipped based upon Merck's order quantities through October 2006.

Expenses:

Total operating expenses decreased to $39.9 million in the first quarter of 2006 from $44.5 million in the same period of 2005, due, in part, to our lower headcount. Our average headcount declined to 587 in the first quarter of 2006 from 734 in the same period of 2005 primarily as a result of workforce reductions made in the fourth quarter of 2005. (See "Severance Costs" below.)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3816

Samsung Bioepis Exhibit 1017, pg. 3816

Operating expenses in the first quarter of 2006 and 2005 include a total of $3.9 million and $5.4 million of Stock Option Expense, respectively, as detailed below:

(In millions)	For the three months ended March 31, 2006		
Expenses	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 30.1	$ 2.0	$ 32.1
Contract manufacturing	1.8	0.1	1.9
General and administrative	4.1	1.8	5.9
Total operating expenses	$ 36.0	$ 3.9	$ 39.9

(In millions)	For the three months ended March 31, 2005		
Expenses	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 32.5	$ 3.4	$ 35.9
Contract manufacturing	2.5	—	2.5
General and administrative	4.1	2.0	6.1
Total operating expenses	$ 39.1	$ 5.4	$ 44.5

Research and Development Expenses:

Research and development expenses decreased to $32.1 million in the first quarter of 2006 from $35.9 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2006 and 2005:

(In millions)	Three months ended March 31,		
Research and development expenses	2006	2005	Increase (Decrease)
Payroll and benefits (1)	$ 10.0	$ 14.4	$ (4.4)
Clinical trial expenses	3.4	2.1	1.3
Clinical manufacturing costs (2)	9.3	9.0	0.3
Research and preclinical development costs	3.5	4.9	(1.4)
Occupancy and other operating costs	5.9	5.5	0.4
Total research and development	$ 32.1	$ 35.9	$ (3.8)

(1) Includes $1.6 million and $3.0 million of Stock Option Expense for the three months ended March 31, 2006 and 2005, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.3 million and $0.4 million of Stock Option Expense for the three months ended March 31, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in the first quarter of 2006, as described above. Clinical trial expenses increased due to higher 2006 costs associated with (i) preparation for initiating a VEGF Trap-Eye phase 2 clinical trial in wet AMD utilizing intravitreal injections in the first half of 2006 and (ii) several IL-1 Trap clinical studies that were initiated in the fourth quarter of 2005. Clinical manufacturing costs increased as higher costs in 2006 related to manufacturing VEGF Trap clinical supplies were partially offset by lower costs

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3817

Samsung Bioepis Exhibit 1017, pg. 3817

related to manufacturing IL-1 Trap clinical supplies. Research and preclinical development costs decreased primarily as a function of our lower 2006 headcount. Occupancy and other operating costs increased primarily due to higher costs for utilities in 2006.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased to $1.9 million in the first quarter of 2006 from $2.5 million in the comparable quarter of 2005. Although we shipped more product to Merck in the first quarter of 2006 than the comparable quarter of 2005, we incurred higher expenses in 2005 resulting from unfavorable manufacturing costs which were expensed in the period incurred.

General and Administrative Expenses:

General and administrative expenses decreased to $5.9 million in the first quarter of 2006 from $6.1 million in the same period of 2005. In 2006, lower administrative personnel costs and legal expenses related to general corporate matters were partly offset by higher patent- related expenses.

Other Income and Expense:

As described above, in January 2005 we received a one-time $25.0 million payment from sanofi-aventis, which was recognized as other contract income in the first quarter of 2005.

Investment income increased to $3.5 million in the first quarter of 2006 from $2.2 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was $3.0 million in the first quarter of 2006 and 2005. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Procter & Gamble, and Merck, and investment income.

Three Months Ended March 31, 2006 and 2005

Cash Provided by Operations:

At March 31, 2006, we had $324.2 million in cash, cash equivalents, and marketable securities compared with $316.7 million at December 31, 2005. In January 2006, we received a $25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3818

Samsung Bioepis Exhibit 1017, pg. 3818

In the first quarter of 2006, our net loss was $20.4 million, however cash provided by our operations was $5.3 million, principally because the above-described $25.0 million payment from sanofi-aventis was receivable at December 31, 2005 and paid in January 2006. In the first quarter of 2005, our net loss was $4.1 million, however cash provided by operations was $33.1 million, principally due to our receipt from sanofi-aventis in the first quarter of 2005 of outstanding year-end 2004 receivables for (i) reimbursement of VEGF Trap development expenses incurred by us and (ii) a $25.0 million clinical milestone payment earned in December 2004.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was $10.9 million in the first quarter of 2006 compared to net cash provided by investing activities of $18.4 million in the same period in 2005, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first quarter of 2006, purchases of marketable securities exceeded sales or maturities by $10.2 million, whereas in the first quarter of 2005, sales or maturities of marketable securities exceeded purchases by $19.8 million.

Cash Provided by Financing Activities:

Cash provided by financing activities increased to $3.4 million in the first quarter of 2006 from $1.0 million in the same period in 2005 due to an increase in issuances of Common Stock in connection with exercises of stock options.

The sanofi-aventis Group Agreement:

Under our collaboration agreement with sanofi-aventis, agreed upon worldwide VEGF Trap development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of a VEGF Trap product for intraocular delivery to the eye predates the first commercial sale of a VEGF Trap product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to $7.5 million of VEGF Trap development expenses in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs. We and sanofi-aventis plan to initiate in 2006 multiple additional clinical studies to evaluate the VEGF Trap as both a single agent and in combination with other therapies in various cancer indications.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of VEGF Trap development expenses will terminate and we will retain all rights to the VEGF Trap.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3819

Samsung Bioepis Exhibit 1017, pg. 3819

Severance Costs:

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of our collaboration with Procter & Gamble, and the expected completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005, with the remainder planned for 2006 following the completion of our contract manufacturing activities for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included $0.2 million of non-cash expenses. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and are being expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. We estimate that total costs associated with the 2005 and planned 2006 workforce reductions will approximate $2.6 million, of which $2.2 million was charged to expense in the fourth quarter of 2005 and $0.2 million was charged to expense in the first quarter of 2006. We anticipate cost savings of approximately $8 million in 2006 resulting from the implementation of our workforce reduction.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $0.6 million and $1.6 million for the first three months of 2006 and 2005, respectively. During the remainder of 2006, we expect to incur approximately $4 million to $6 million in capital expenditures which will primarily consist of equipment for our manufacturing, research, and development activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). We currently anticipate that approximately 55%-65% of our expenditures for 2006 will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap; approximately 20%-25% of our expenditures for 2006 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2006 will be used for capital expenditures and general corporate purposes.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaboration with sanofi-aventis. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3820

Samsung Bioepis Exhibit 1017, pg. 3820

manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least mid-2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of March 31, 2006, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In January 2005, we filed a shelf registration statement on Form S-3 to sell, in one or more offerings, up to $200.0 million of equity or debt securities, together or separately, which registration statement was declared effective in February 2005. However, there is no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

During the three months ended March 31, 2006, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2005.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3821

Samsung Bioepis Exhibit 1017, pg. 3821

an approximately $0.9 million and $1.2 million change in the fair market value of our investment portfolio at March 31, 2006 and 2005, respectively. The decrease in the impact of an interest rate change at March 31, 2006, compared to March 31, 2005, is due to decreases in our investment portfolio's balance and duration to maturity at the end of March 2006 versus the end of March 2005.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2005 and should be considered by our investors.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3822

Samsung Bioepis Exhibit 1017, pg. 3822

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2006, we had a cumulative loss of $605.7 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We currently receive contract manufacturing revenue from our agreement with Merck and, until June 30, 2005, we received contract research and development revenue from our agreement with The Procter & Gamble Company. Our agreement with Procter & Gamble expired in June 2005 and our agreement with Merck will expire before the end of 2006. The expiration of these agreements results in a significant loss of revenue to the Company.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least mid-2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3823

Samsung Bioepis Exhibit 1017, pg. 3823

principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap in a variety of systemic inflammatory disorders. Most of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3824

Samsung Bioepis Exhibit 1017, pg. 3824

determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of the IL-1 Trap in different diseases after a phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate (s), and our business, financial condition, and results of operations may be materially harmed.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

Although the IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events in the phase 2 rheumatoid arthritis study completed in 2003, safety or tolerability concerns may arise as we test higher doses of the IL-1 Trap in patients with other

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3825

Samsung Bioepis Exhibit 1017, pg. 3825

inflammatory diseases and disorders. Like TNF-antagonists such as Enbrel® (Amgen) and Remicade® (Centocor), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, there may be an increased risk for infections to develop in patients treated with the IL-1 Trap. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the IL-1 Trap.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date — in some cases even after pivotal clinical trials have been completed. Subjects who received the IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap develop antibodies to the product candidate.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap, VEGF Trap-Eye, IL-1 Trap, and IL-4/13 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3826

Samsung Bioepis Exhibit 1017, pg. 3826

the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap or VEGF Trap-Eye or in a damage award.

We are aware of certain United States and foreign patents relating to particular IL-4 and IL-13 receptors. Our IL-4/13 Trap includes portions of the IL-4 and IL-13 receptors. In addition, we are aware of a broad patent held by Genentech relating to proteins fused to certain immunoglobulin domains. Our Trap product candidates include proteins fused to immunoglobulin domains. Although we do not believe that we are infringing valid and enforceable third party patents, the holders of these patents may sue us for infringement and a court may find that we are infringing one or more validly issued patents, which may materially harm our business.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3827

Samsung Bioepis Exhibit 1017, pg. 3827

drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3828

Samsung Bioepis Exhibit 1017, pg. 3828

accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2005, which report was included in our Annual Report on Form 10-K for the year ended December 31, 2005. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3829

Samsung Bioepis Exhibit 1017, pg. 3829

particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3830

Samsung Bioepis Exhibit 1017, pg. 3830

or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. Under a long-term manufacturing agreement with Merck, which expires in October 2006, we produce an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. We also use our facilities to produce API for our own clinical and preclinical candidates. When we no longer use our facilities to manufacture the Merck intermediate or if clinical candidates are discontinued, we will have to absorb overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3831

Samsung Bioepis Exhibit 1017, pg. 3831

European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote siguificant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Onyx Pharmaceuticals and Bayer have received approval from the FDA to market and sell the first oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3832

Samsung Bioepis Exhibit 1017, pg. 3832

antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the Onyx/Bayer kinase inhibitor, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye diseases is also very competitive. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor for age-related macular degeneration (wet AMD). Novartis and Genentech are collaborating on the development of a VEGF antibody fragment for the treatment of wet AMD that is in phase 3 development. In December 2005, Genentech announced that it filed an application with the FDA to market and sell this VEGF inhibitor in patients with wet AMD. In addition, it has been reported that ophthalmologists are using a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The marketing approval of the OSI/Pfizer VEGF inhibitor and the potential off-label use of Avastin and approval of the Novartis/Genentech VEGF antibody fragment make it more difficult for us to successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it will be difficult for our drug to compete against the OSI/Pfizer drug and, if approved by the FDA, the Novartis/Genentech VEGF inhibitor, because doctors and patients will have significant experience using these medicines. Moreover, the relatively low cost of therapy with Avastin in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Amgen), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have siguificant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Novartis is developing an antibody to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3833

Samsung Bioepis Exhibit 1017, pg. 3833

We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the *CIAS*1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers.

Sales of biopharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payers, the market for any biopharmaceutical product will be limited. These third-party payers increasingly challenge the price and examine the cost-effectiveness of products and services. Significant uncertainty exists as to the reimbursement status of any new therapeutic, particularly if there exist lower-cost standards of care. Third-party payers may not reimburse sales of our products, which would harm our business.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, Murray A. Goldberg, our Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, Neil Stahl, Ph.D., our Senior Vice President, Preclinical Development and Biomolecular Science, and Randall G. Rupp, Ph.D., our Senior Vice President, Manufacturing Operations. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3834

Samsung Bioepis Exhibit 1017, pg. 3834

- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of April 13, 2006, our seven largest shareholders, including sanofi-aventis, beneficially owned 47.9% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 13, 2006. As of April 13, 2006, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 5.1% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, through September 5, 2006, sanofi-aventis may sell no more than 250,000 of these shares in any calendar quarter. After September 5, 2006, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 13, 2006, holders of Class A Stock held 4.1% of all shares of Common Stock and Class A Stock then outstanding, and had 29.7% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 13, 2006:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3835

Samsung Bioepis Exhibit 1017, pg. 3835

- our current officers and directors beneficially owned 14.6% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2006, and 33.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2006; and
- our seven largest shareholders beneficially owned 47.9% of our outstanding shares of Common Stock assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 13, 2006. In addition, these seven shareholders held 54.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of April 13, 2006.

The anti-takeover effects of provisions of our charter, by-laws, and rights agreement, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws, our rights agreement and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3836

Samsung Bioepis Exhibit 1017, pg. 3836

- under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

We have a shareholder rights plan which could make it more difficult for a third party to acquire us without the support of our board of directors and principal shareholders. In addition, many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of the Company, as defined in the plan.

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
12.1	— Statement re: computation of ratio of earnings to combined fixed charges.
31.1	— Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	— Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	— Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3837

Samsung Bioepis Exhibit 1017, pg. 3837

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: May 8, 2006

By: /s/ Murray A. Goldberg
Murray A. Goldberg
Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3838

Samsung Bioepis Exhibit 1017, pg. 3838

Exhibit 12.1

Regeneron Pharmaceuticals, Inc.
Computation of Ratio of Earnings to Combined Fixed Charges
(Dollars in thousands)

	Years ended December 31,					Three months ended March 31,
	2001	2002	2003	2004	2005	2006
Earnings:						
Income (loss) from continuing operations before income (loss) from equity investee	($75,178)	($124,350)	($107,395)	$41,565	($95,456)	(21,193)
Fixed charges	3,888	13,685	14,108	14,060	13,687	3,412
Amortization of capitalized interest	—	—	33	78	78	19
Interest capitalized	—	(222)	(276)	—	—	—
Adjusted earnings	($71,290)	($110,887)	($ 93,530)	$55,703	($81,691)	($ 17,762)
Fixed charges:						
Interest expense	$ 2,657	$ 11,859	$ 11,932	$12,175	$ 12,046	$ 3,011
Interest capitalized	—	222	276	—	—	—
Assumed interest component of rental charges	1,231	1,604	1,900	1,885	1,641	401
Total fixed charges	$ 3,888	$ 13,685	$ 14,108	$14,060	$ 13,687	$ 3,412
Ratio of earnings to fixed charges	(A)	(A)	(A)	3.96	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2001, 2002, 2003, and 2005, and for the three months ended March 31, 2006, the ratio coverage was less than 1:1. To achieve a coverage ration of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

	Years ended December 31,				Three months ended March 31,
	2001	2002	2003	2005	2006
Coverage deficiency	$ 75,178	$124,572	$107,638	$ 95,378	$ 21,174

Exhibit 31.1

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2006

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 31.2

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2006

/s/ Murray A. Goldberg
Murray A. Goldberg
Senior Vice President, Finance &
Administration, Chief Financial Officer,
Treasurer,and Assistant Secretary

Exhibit 32

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
May 8, 2006

/s/ Murray A. Goldberg

Murray A. Goldberg
Chief Financial Officer
May 8, 2006

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 8/8/2006

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2006

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of July 31, 2006:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,296,928
Common Stock, $0.001 par value	54,674,613

REGENERON PHARMACEUTICALS, INC.
Table of Contents
June 30, 2006

	Page Numbers
PART I FINANCIAL INFORMATION	
Item 1 Financial Statements	
Condensed balance sheets (unaudited) at June 30, 2006 and December 31, 2005	3
Condensed statements of operations (unaudited) for the three and six months ended June 30, 2006 and 2005	4
Condensed statement of stockholders' equity (unaudited) for the six months ended June 30, 2006	5
Condensed statements of cash flows (unaudited) for the six months ended June 30, 2006 and 2005	6
Notes to condensed financial statements (unaudited)	7-18
Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations	19-36
Item 3 Quantitative & Qualitative Disclosure About Market Risk	37
Item 4 Controls and Procedures	37
PART II OTHER INFORMATION	
Item 1 Legal Proceedings	37
Item 1A Risk Factors	37-52
Item 4 Submission of Matters to a Vote of Security Holders	52
Item 6 Exhibits	53
SIGNATURE PAGE	54
EX-12.1: STATEMENT RE: COMPUTATION OF EARNINGS TO COMBINED FIXED CHARGES	
EX-31.1: CERTIFICATION	
EX-31.2: CERTIFICATION	
EX-32: CERTIFICATION	

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT JUNE 30, 2006 AND DECEMBER 31, 2005 (Unaudited)
(In thousands, except share data)

	June 30, 2006	December 31, 2005
ASSETS		
Current assets		
Cash and cash equivalents	$ 114,960	$ 184,508
Marketable securities	158,616	114,037
Accounts receivable	12,141	36,521
Prepaid expenses and other current assets	3,211	3,422
Inventory	2,128	2,904
Total current assets	291,056	341,392
Marketable securities	30,507	18,109
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	53,854	60,535
Other assets	2,915	3,465
Total assets	$ 378,332	$ 423,501
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 16,466	$ 23,337
Deferred revenue, current portion	15,042	17,020
Total current liabilities	31,508	40,357
Deferred revenue	63,057	69,142
Notes payable	200,000	200,000
Total liabilities	294,565	309,499
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,296,928 in 2006 and 2,347,073 in 2005	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 54,669,695 in 2006 and 54,092,268 in 2005	55	54
Additional paid-in capital	713,419	700,011
Unearned compensation		(315)
Accumulated deficit	(629,236)	(585,280)
Accumulated other comprehensive loss	(473)	(470)
Total stockholders' equity	83,767	114,002
Total liabilities and stockholders' equity	$ 378,332	$ 423,501

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3848

Samsung Bioepis Exhibit 1017, pg. 3848

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2006	2005	2006	2005
Revenues				
Contract research and development	$ 14,991	$ 13,545	$ 29,578	$ 27,047
Contract manufacturing	4,267	2,821	7,899	5,528
	19,258	16,366	37,477	32,575
Expenses				
Research and development	34,398	40,642	66,482	76,554
Contract manufacturing	2,810	1,675	4,662	4,166
General and administrative	6,299	6,216	12,245	12,362
	43,507	48,533	83,389	93,082
Loss from operations	(24,249)	(32,167)	(45,912)	(60,507)
Other income (expense)				
Other contract income		5,640		30,640
Investment income	3,684	2,539	7,165	4,769
Interest expense	(3,011)	(3,011)	(6,022)	(6,024)
	673	5,168	1,143	29,385
Net loss before cumulative effect of a change in accounting principle	(23,576)	(26,999)	(44,769)	(31,122)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")			813	
Net loss	$ (23,576)	$ (26,999)	$ (43,956)	$ (31,122)
Net loss per share amounts, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	$ (0.41)	$ (0.48)	$ (0.79)	$ (0.56)
Cumulative effect of adopting SFAS 123R			0.02	
Net loss	$ (0.41)	$ (0.48)	$ (0.77)	$ (0.56)
Weighted average shares outstanding, basic and diluted	56,915	55,917	56,821	55,866

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3849

Samsung Bioepis Exhibit 1017, pg. 3849

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
For the six months ended June 30, 2006
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount						
Balance, December 2005	2,347	$2	54,092	$54	$700,011	$(315)	$(585,280)	$(470)	$114,002	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			409	1	3,812				3,813	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contributio			121		1,884				1,884	
Conversion of Class A Stock to Common Stock	(50)		50							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(2)							
Stock-based compensation expense					8,840				8,840	
Adjustment to reduce unearned compensati upon adoption of SFAS 123R					(315)	315				
Cumulative effect of adopting SFAS 123R					(813)				(813)	
Net loss							(43,956)		(43,956)	$(43,956)
Change in net unrealized loss on marketable securities								(3)	(3)	(3)
Balance, June 30, 2006	2,297	$2	54,670	$55	$713,419	—	$(629,236)	$(473)	$ 83,767	$(43,959)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Six months ended June 30, 2006	2005
Cash flows from operating activities		
Net loss	$ (43,956)	$ (31,122)
Adjustments to reconcile net loss to net cash provided by operating activities		
Depreciation and amortization	7,488	7,689
Non-cash compensation expense	8,779	11,703
Cumulative effect of a change in accounting principle	(813)	
Changes in assets and liabilities		
Decrease in accounts receivable	24,380	26,272
Decrease (increase) in prepaid expenses and other assets	627	(1,246)
Decrease in inventory	1,279	141
Decrease in deferred revenue	(8,063)	(6,848)
Decrease in accounts payable, accrued expenses, and other liabilities	(5,118)	(2,040)
Total adjustments	28,559	35,671
Net cash (used in) provided by operating activities	(15,397)	4,549
Cash flows from investing activities		
Purchases of marketable securities	(152,660)	(60,392)
Sales or maturities of marketable securities	95,292	107,680
Capital expenditures	(986)	(2,897)
Net cash (used in) provided by investing activities	(58,354)	44,391
Cash flows from financing activities		
Net proceeds from the issuance of stock	3,813	1,032
Other	390	
Net cash provided by financing activities	4,203	1,032
Net (decrease) increase in cash and cash equivalents	(69,548)	49,972
Cash and cash equivalents at beginning of period	184,508	95,229
Cash and cash equivalents at end of period	$ 114,960	$ 145,201

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3852

Samsung Bioepis Exhibit 1017, pg. 3852

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2005 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. For the three and six months ended June 30, 2006 and 2005, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended June 30,	
	2006	2005
Net loss (Numerator)	$(23,576)	$(26,999)
Weighted-average shares, in thousands (Denominator)	56,915	55,917
Basic and diluted net loss per share	$ (0.41)	$ (0.48)

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3853

Samsung Bioepis Exhibit 1017, pg. 3853

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Six Months Ended June 30,	
	2006	2005
Net loss (Numerator)	$(43,956)	$(31,122)
Weighted-average shares, in thousands (Denominator)	56,821	55,866
Basic and diluted net loss per share	$ (0.77)	$ (0.56)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the June 30, 2006 and 2005 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended June 30,	
	2006	2005
Stock Options:		
Weighted average number, in thousands	14,181	13,295
Weighted average exercise price	$ 14.32	$ 14.55
Restricted Stock:		
Weighted average number, in thousands	40	204
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

	Six months ended June 30,	
	2006	2005
Stock Options:		
Weighted average number, in thousands	14,291	13,385
Weighted average exercise price	$ 14.29	$ 14.64
Restricted Stock:		
Weighted average number, in thousands	47	209
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3854

Samsung Bioepis Exhibit 1017, pg. 3854

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

3. Stock-based Employee Compensation

Adoption of Statement of Financial Accounting Standards Nos. 123 and 123R

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by $813 and is included in the Company's operating results for the six months ended June 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on the Company's loss from operations, net loss, and net loss per share for the three and six months ended June 30, 2006 was not significant, and there was no impact to the Company's cash flows for these respective periods.

Long-Term Incentive Plans

The Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan"), as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, certain shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals,

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3855

Samsung Bioepis Exhibit 1017, pg. 3855

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. The 1990 Incentive Plan, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. The 1990 Incentive Plan has expired and there will be no future awards from the 1990 Incentive Plan. The Company has issued Incentive Stock Options ("ISOs") and Nonqualified Stock Options, and shares of Restricted Stock from the 1990 and 2000 Incentive Plans. The terms of the awards are determined by the Compensation Committee of the board of directors; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the ISO is granted and no ISO is exercisable more than ten years after the date of grant. As of June 30, 2006, there were 6,495,452 shares available for future grants under the 2000 Incentive Plan.

a. Stock Options

At June 30, 2006, there were 14,150,178 stock options outstanding with exercise prices ranging from $4.83 to $51.56. Options granted to employees generally vest annually on a pro rata basis over a four to five year period beginning one year from the date of grant. Certain performance-based options granted to the Company's executive vice president and senior vice presidents in January 2005 vest if both (i) the Company's products have achieved defined sales targets and (ii) the option recipient has remained employed by the Company for at least three years from the date of grant. Options granted to members of the Company's board of directors vest annually on a pro rata basis over three years beginning one year from the date of grant. A summary of the Company's stock option activity for the six months ended June 30, 2006 is presented in the following table:

	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Intrinsic Value (in thousands)
Stock options outstanding at January 1, 2006	14,719,492		$ 14.23	
Stock options granted	206,500		$ 15.32	
Stock options exercised	(438,031)		$ 9.82	
Stock options forfeited	(201,135)		$ 10.62	
Stock options expired	(136,648)		$ 25.24	
Stock options outstanding at June 30, 2006	14,150,178	6.5	$ 14.32	$ 28,313
Stock options vested and exercisable	7,193,872	5.1	$ 17.70	$ 12,185

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3856

Samsung Bioepis Exhibit 1017, pg. 3856

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

The total intrinsic value of stock options exercised during the first six months of 2006 and 2005 was $2,863 and $200, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

For the three months ended June 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") totaled $4,610 and $5,398, respectively, of which $4,585 and $5,348 was recognized in operating expenses and $25 and $50 was capitalized into inventory, respectively. For the six months ended June 30, 2006 and 2005, Stock Option Expense totaled $8,541 and $10,939, respectively, of which $8,481 and $10,727 was recognized in operating expenses and $60 and $212 was capitalized into inventory, respectively. As of June 30, 2006, there was $23,243 of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.7 years. In addition, there are 723,092 options which are unvested as of June 30, 2006 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals $2,688 and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Fair Value Assumptions:

The fair value of each option granted during the three and six months ended June 30, 2006 and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and board directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The weighted-average fair value of the options granted during the three months ended June 30, 2006 and 2005 was $8.23 and $4.04 per option, respectively. The weighted-average fair value of the options granted during the six months ended June 30, 2006 and 2005 was $10.28 and $5.81 per option, respectively. The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3857

Samsung Bioepis Exhibit 1017, pg. 3857

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended June 30,	
	2006	2005
Expected volatility	65 %	70 %
Expected lives from grant date	5.2 years	5.0 years
Expected dividend yield	0 %	0 %
Risk-free interest rate	4.95 %	3.78 %

	Six months ended June 30,	
	2006	2005
Expected volatility	68 %	75 %
Expected lives from grant date	6.8 years	6.2 years
Expected dividend yield	0 %	0 %
Risk-free interest rate	4.76 %	3.96 %

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the six months ended June 30, 2006 is presented in the following table:

	Number of Shares	Weighted Average Grant Date Fair Value
Restricted stock outstanding as of January 1, 2006	95,188	$ 11.16
Restricted stock released	(93,485)	$ 11.18
Restricted stock forfeited	(1,703)	$ 9.74
Restricted stock outstanding as of June 30, 2006	—	

In accordance with generally accepted accounting principles, the Company recorded unearned compensation in Stockholders' Equity related to these Restricted Stock awards. The amount was based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restrictions lapse, which is approximately two years for grants issued in 2003 and 18 months for grants issued in 2004. No Restricted Stock awards were granted in 2005 or during the six months ended June 30, 2006. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation was combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

For the three months ended June 30, 2006 and 2005, the Company recognized compensation expense related to Restricted Stock awards of $115 and $474, respectively. For the six months ended June 30, 2006 and 2005, the Company recognized

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3858

Samsung Bioepis Exhibit 1017, pg. 3858

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

compensation expense related to Restricted Stock awards of $299 and $976, respectively. As of June 30, 2006, there were no unvested shares of restricted stock outstanding and all compensation expense related to these awards had been recognized.

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2006 and December 31, 2005 are $216 and $234, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 2005 and December 31, 2004 are $1,393 and $550, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2005 and 2004 are $1,884 and $632, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2006 and 2005, the Company contributed 120,960 and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at June 30, 2006 and December 31, 2005 are $840 and $1,228, respectively, of accrued interest income. Included in marketable securities at June 30, 2005 and December 31, 2004 are $2,562 and $2,601, respectively, of accrued interest income.

5. Severance Costs

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the expected completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005, with the remainder planned for 2006 following the completion of the Company's contract manufacturing activities for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and are being expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. The Company

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3859

Samsung Bioepis Exhibit 1017, pg. 3859

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

estimates that total costs associated with the 2005 and planned 2006 workforce reductions will approximate $2.6 million, including $0.2 million of non-cash expenses in 2005.

Severance costs associated with the workforce reduction plan that were charged to expense during the three and six months ended June 30, 2006 consist of the following:

		Three months ended June 30, 2006		
	Accrued liability at March 31, 2006	Costs charged to expense	Costs paid or settled in 2006	Accrued liability at June 30, 2006
Employee severance, payroll taxes, and benefits	$ 425	$ 197	$ 159	$ 463
Other severance costs	—	6	5	1
Total	$ 425	$ 203	$ 164	$ 464

		Six months ended June 30, 2006		
	Accrued liability at December 31, 2005	Costs charged to expense	Costs paid or settled in 2006	Accrued liability at June 30, 2006
Employee severance, payroll taxes, and benefits	$ 907	$ 356	$ 800	$ 463
Other severance costs	176	19	194	1
Total	$ 1,083	$ 375	$ 994	$ 464

These severance costs are included in the Company's Statement of Operations for the three and six months ended June 30, 2006 as follows:

Three months ended June 30, 2006	Research & development
Employee severance, payroll taxes, and benefits	$ 197
Other severance costs	6
Total	$ 203

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3860

Samsung Bioepis Exhibit 1017, pg. 3860

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

Six months ended June 30, 2006	Research & development	General & administrative
Employee severance, payroll taxes, and benefits	$ 358	$ (2)
Other severance costs	19	—
Total	$ 377	$ (2)

For segment reporting purposes (see Note 10), all severance-related expenses are included in the Research & Development segment.

6. Accounts Receivable

Accounts receivable as of June 30, 2006 and December 31, 2005 consist of the following:

	June 30, 2006	December 31, 2005
Receivable from the sanofi-aventis Group	$ 11,773	$ 36,412
Receivable from Merck & Co., Inc.	368	27
Other	—	82
	$ 12,141	$ 36,521

7. Inventories

Inventories consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which will expire in October 2006.

Inventories as of June 30, 2006 and December 31, 2005 consist of the following:

	June 30, 2006	December 31, 2005
Raw materials	—	$ 278
Work-in-process	—	1,423
Finished products	$ 2,128	1,203
	$ 2,128	$ 2,904

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3861

Samsung Bioepis Exhibit 1017, pg. 3861

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

8 Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2006 and December 31, 2005 consist of the following:

	June 30, 2006	December 31, 2005
Accounts payable	$ 2,840	$ 4,203
Accrued payroll and related costs	6,223	10,713
Accrued clinical trial expense	3,434	3,081
Accrued expenses, other	1,677	3,048
Interest payable on convertible notes	2,292	2,292
	$ 16,466	$ 23,337

9. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three and six months ended June 30, 2006 and 2005, the components of comprehensive loss are:

	Three months ended June 30,	
	2006	2005
Net loss	$ (23,576)	$ (26,999)
Change in net unrealized gain (loss) on marketable securities	(102)	401
Total comprehensive loss	$ (23,678)	$ (26,598)

	Six months ended June 30,	
	2006	2005
Net loss	$ (43,956)	$ (31,122)
Change in net unrealized gain (loss) on marketable securities	(3)	60
Total comprehensive loss	$ (43,959)	$ (31,062)

10. Segment Information

The Company's operations are managed in two business segments: research and development, and contract manufacturing.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3862

Samsung Bioepis Exhibit 1017, pg. 3862

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and (ii) the supply of research materials based on Regeneron-developed proprietary technology.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. The Company produces an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which will expire in October 2006.

The table below presents information about reported segments for the three and six months ended June 30, 2006 and 2005.

	Three months ended June 30, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 14,991	$4,267	—	$ 19,258
Depreciation and amortization	3,429	— (1)	$ 261	3,690
Non-cash compensation expense	4,603	97	—	4,700
Interest expense	—	—	3,011	3,011
Net (loss) income	(25,706)	1,457	673 (2)	(23,576)
Capital expenditures	323	—	—	323

	Three months ended June 30, 2005			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 13,545	$2,821	—	$ 16,366
Depreciation and amortization	3,570	— (1)	$ 261	3,831
Non-cash compensation expense	5,732	90	—	5,822
Other contract income	5,640	—	—	5,640
Interest expense	—	—	3,011	3,011
Net (loss) income	(27,673)	1,146	(472)(2)	(26,999)
Capital expenditures	2,115	—	—	2,115

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3863

Samsung Bioepis Exhibit 1017, pg. 3863

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Six months ended June 30, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 29,578	$7,899	—	$ 37,477
Depreciation and amortization	6,966	— (1)	$ 522	7,488
Non-cash compensation expense	8,587	192	(813)(3)	7,966
Interest expense	—	—	6,022	6,022
Net (loss) income	(49,149)	3,237	1,956 (2)	(43,956)
Capital expenditures	968	—	—	968
Total assets	64,543	3,580	310,209 (4)	378,332

	Six months ended June 30, 2005			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 27,047	$5,528	—	$ 32,575
Depreciation and amortization	7,167	— (1)	$ 522	7,689
Non-cash compensation expense	11,613	90	—	11,703
Other contract income	30,640	—	—	30,640
Interest expense	—	—	6,024	6,024
Net (loss) income	(31,229)	1,362	(1,255)(2)	(31,122)
Capital expenditures	3,752	—	—	3,752
Total assets	81,936	6,006	359,006 (4)	446,948

(1) Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

(2) Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the six months ended June 30, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 3).

(3) Represents the cumulative effect of adopting SFAS 123R (see Note 3).

(4) Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3864

Samsung Bioepis Exhibit 1017, pg. 3864

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: VEGF Trap in oncology, VEGF Trap eye formulation (VEGF Trap-Eye) in eye diseases using intraocular delivery, and IL-1 Trap in various inflammatory indications. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse pipeline of product candidates that we believe has the potential to address a variety of serious medical conditions. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the strength of the VelocImmune platform, which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move two new antibody candidates into clinical trials each year going forward beginning in 2007. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3865

Samsung Bioepis Exhibit 1017, pg. 3865

Clinical Programs:

Below is a summary of the clinical status of our clinical candidates as of June 30, 2006:

1. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regnlator of vascular permeability and leakage.

The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis, as described below. In September 2005, we and sanofi-aventis announced plans to expand our joint development program, and we have subsequently initiated a broad set of clinical trials in oncology.

In the first half of 2006, we and sanofi-aventis initiated our phase 2 single-agent program for the VEGF Trap in cancer. Patient enrollment is now underway in studies in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the United States Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for the treatment of SMA.

The companies also plan to conduct three phase 3 efficacy/safety trials using the VEGF Trap in combination with standard chemotherapy regimens, the first of which is planned to begin in late 2006 or early 2007, once the supporting safety and tolerability studies have been completed. The companies are working to finalize plans with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) to conduct at least ten additional cancer trials, several of which are planned to begin in 2006.

Currently there are five safety and tolerability studies underway for the VEGF Trap in combination with standard chemotherapy regimens designed to support subsequent phase 3 clinical trials in a variety of cancer types. At the annual meeting of the American Society of Clinical Oncology (ASCO) in May 2006, the companies reported abstracts summarizing information from two of these studies. The first study is evaluating the VEGF Trap plus oxaliplatin, 5-flourouracil, and leucovorin (FOLFOX4) in a phase 1 trial of patients with advanced solid tumors. The second study is evaluating the VEGF Trap plus irinotecan, 5-fluorouracil, and leucovorin (LV5FU2-CPT11) in a phase 1 trial of patients with advanced solid tumors. In both trials, patients have been treated in combination with chemotherapy in doses ranging up to 4.0 milligrams per kilogram (mg/kg) of the VEGF Trap. The abstracts, published in the 2006 ASCO Annual Meeting Proceedings, reported that the VEGF Trap could be safely combined with either FOLFOX4 or LV5FU2-CPT11 at the dose levels studied. The maximum tolerated doses in these studies have not yet been reached, and dose escalation is continuing.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3866

Samsung Bioepis Exhibit 1017, pg. 3866

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to $400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to $360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another $40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. (See "The sanofi-aventis Group Agreement" below.)

2. VEGF Trap — Eye Diseases

We are developing the VEGF Trap-Eye for the treatment of certain eye diseases. This product candidate has been purified and formulated in concentrations suitable for direct injection into the eye. We retain the exclusive right to develop and commercialize the VEGF Trap-Eye for the treatment of eye diseases utilizing local (intravitreal) delivery to the eye. In May 2006, we

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3867

Samsung Bioepis Exhibit 1017, pg. 3867

announced that we had initiated a phase 2 trial of the VEGF Trap-Eye delivered intravitreally in patients with the neovascular form of age-related macular degeneration (wet AMD).

At the May 2006 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO), we reported positive preliminary results from a phase 1 trial of the VEGF Trap-Eye in patients with wet AMD. A total of 21 patients received a single dose of VEGF Trap-Eye at doses of 0.05, 0.15, 0.5, 1, 2, and 4 milligrams (mg) intravitreally (direct injection into the eye). Patients were evaluated for six weeks to measure the durability of effects and provide guidance for dosing regimens to be used in future trials. All dose levels were generally well tolerated, and a maximum tolerated dose was not reached in the study. In wet AMD, the leakiness of the abnormal blood vessels in the eye can lead to increased retinal thickness. On average, patients receiving the VEGF Trap-Eye demonstrated large, rapid, and sustained (at least six weeks) reductions in retinal thickness. Excess retinal thickness, as determined by ocular coherence tomography (OCT), is a clinical measure of disease activity in wet AMD. As measured by the OCT reading center (posterior pole OCT scans), the median excess retinal thickness resulting from the disease process was 194 microns at baseline. Following a single intravitreal dose of the VEGF Trap-Eye, median excess retinal thickness was reduced to 60 microns, an improvement that was sustained over a six week period. As measured by the computerized Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline, which was reduced to 27 microns at six weeks after the single dose of the VEGF Trap-Eye.

Of the 20 patients evaluable for efficacy, 95 percent had stabilization or improvement in visual acuity, defined as ≤15 letter loss on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. Patients were also evaluated for best-corrected visual acuity (BCVA), the best acuity a person can achieve with glasses. BCVA for all patients in the study increased by a mean of 4.8 letters at six weeks. In the two highest dose groups (2 mg and 4 mg), the mean improvement in BCVA was 13.5 letters, with three of six patients showing an improvement in BCVA of 15 or more letters.

In the second quarter of 2006, we initiated a 150 patient, 12 week, phase 2 trial of the VEGF Trap-Eye in wet AMD. The trial is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. A phase 3 trial of the VEGF Trap-Eye in wet AMD is planned to begin in early 2007.

Also in the second quarter of 2006, we initiated a small pilot study of the VEGF Trap in patients with diabetic macular edema.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis™ (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3868

Samsung Bioepis Exhibit 1017, pg. 3868

edema and neovascular proliferation. It is estimated that in the U.S. 6% of individuals aged 65-74 and 20% of those older than 75 are affected with wet AMD. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

3. IL-1 Trap — Inflammatory Diseases

The IL-1 Trap is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors.

We are evaluating the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called *CIAS1*-Associated Periodic Syndrome (CAPS) and diseases associated with inflammation. These include Systemic Juvenile Idiopathic Arthritis (SJIA) and certain inflammatory vascular diseases.

In April 2006, we completed enrollment of the pivotal study of the IL-1 Trap in patients with CAPS. Patients in the trial are receiving a 160 mg dose of the IL-1 Trap once a week through subcutaneous self-administration. The six-month, placebo-controlled, double-blind, efficacy phase of the study is expected to be completed and preliminary data available by the end of 2006. This phase will be followed by a six-month open-label extension phase. We plan to file a Biologics License Application (BLA) for the IL-1 Trap for the treatment of CAPS in early 2007. In addition, Regeneron has ongoing proof-of-concept studies in other indications, such as SJIA. The FDA has granted Orphan Drug and Fast Track designations to the IL-1 Trap for the treatment of CAPS. In April 2005, the FDA also granted an Orphan Drug designation to the IL-1 Trap for the treatment of SJIA.

An IL-1 receptor antagonist, Kineret® (Amgen Inc.), has been approved by the FDA for the treatment of rheumatoid arthritis. It has been publicly reported that in small trials Kineret appears to reduce the symptoms in CAPS patients and SJIA patients, which supports the role of IL-1 in these diseases. CAPS includes rare genetic disorders, such as Familial Cold Auto-Inflammatory Syndrome (FCAS), Muckle Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disorder (NOMID), which affect a small group of people. Patients with these disorders develop fever, joint aches, headaches, and rashes. In certain indications, these symptoms can be extremely serious. There are no currently approved therapies for CAPS. SJIA is a severe inflammatory disorder which may be debilitating or fatal. It is estimated that there are between 5,000 and 10,000 children with SJIA in the United States.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3869

Samsung Bioepis Exhibit 1017, pg. 3869

are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our IL-1 Trap currently in clinical development.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through June 30, 2006, we had a cumulative loss of $629.2 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the IL-1 Trap; advance new product candidates into clinical development from our existing research programs; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events for 2006 and plans over the next 12 months are as follows:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3870

Samsung Bioepis Exhibit 1017, pg. 3870

Product Candidate	2006 Events to Date	2006-7 Plans
VEGF Trap — Oncology	• Initiated phase 2 studies of the VEGF Trap as a single agent in AOC and NSCLA patients, and in AOC patients with SMA. • Initiated two safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens • Reported encouraging preliminary results of the safety and tolerability of intravenous VEGF Trap plus FOLFOX4 and of intravenous VEGF Trap plus LV5FU2-CPT11 in separate phase 1 trials of patients with advanced solid tumors	• Initiate up to three efficacy/safety studies of the VEGF Trap in combination with standard chemotherapy regimens in different cancer indications • Sponsor with the NCI/CTEP at least ten exploratory efficacy/safety studies evaluating the VEGF Trap in a variety of cancer types
VEGF Trap-Eye	• Reported positive preliminary results from phase 1 trial in wet AMD utilizing intravitreal injections in 21 patients up to a top dose of 4 mg • Initiated phase 2 trial in wet AMD utilizing intravitreal injections • Initiated phase 1 trial in DME	• Report preliminary results of phase 2 trial in wet AMD utilizing intravitreal injections • Initiate phase 3 trial in wet AMD utilizing intravitreal injections • Explore additional eye disease indications
IL-1 Trap	• Completed enrollment of pivotal trial of IL-1 Trap in CAPS • Reported positive preliminary results from ongoing phase 1 trial in SJIA	• Complete efficacy portion of pivotal study in CAPS and, if results show positive efficacy and safety, file Biologics License Application (BLA) with the FDA • Initiate advanced efficacy trial, evaluating the IL-1 Trap for SJIA

Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation- Transition and Disclosure*. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3871

Samsung Bioepis Exhibit 1017, pg. 3871

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by $0.8 million and is included in our operating results for the six months ended June 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on our loss from operations, net loss, and net loss per share for the three and six months ended June 30, 2006 was not significant, and there was no impact to our cash flows for these respective periods.

Non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") totaled $4.6 million for the three months ended June 30, 2006, which was recognized in operating expenses, and $5.4 million for the three months ended June 30, 2005, of which $5.3 million was recognized in operating expenses and $0.1 million was capitalized into inventory. For the six months ended June 30, 2006 and 2005, Stock Option Expense totaled $8.6 million and $10.9 million, respectively, of which $8.5 million and $10.7 million was recognized in operating expenses and $0.1 million and $0.2 million was capitalized into inventory, respectively. As of June 30, 2006, there was $23.2 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.7 years. In addition, there are 723,092 options which are unvested as of June 30, 2006 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals $2.7 million and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3872

Samsung Bioepis Exhibit 1017, pg. 3872

expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average values of the assumptions we used in computing the fair value of option grants during the three and six months ended June 30, 2006 and 2005:

	Three months ended June 30,	
	2006	2005
Expected volatility	65%	70%
Expected lives from grant date	5.2 years	5.0 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.95%	3.78%

	Six months ended June 30,	
	2006	2005
Expected volatility	68%	75 %
Expected lives from grant date	6.8 years	6.2 years
Expected dividend yield	0%	0 %
Risk-free interest rate	4.76%	3.96 %

Changes in any of these estimates may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

Results of Operations

Three Months Ended June 30, 2006 and 2005

Net Loss:

Regeneron reported a net loss of $23.6 million, or $0.41 per share (basic and diluted), for the second quarter of 2006 compared to a net loss of $27.0 million, or $0.48 per share (basic and diluted), for the second quarter of 2005.

Revenues:

Revenues for the three months ended June 30, 2006 and 2005 consist of the following:

(In millions)	2006	2005	Increase (Decrease)
Contract research & development revenue			
The sanofi-aventis Group	$ 14.8	$ 9.4	$ 5.4
The Procter & Gamble Company	—	2.9	(2.9)
Other	0.2	1.3	(1.1)
Total contract research & development revenue	15.0	13.6	1.4
Contract manufacturing revenue	4.3	2.8	1.5
Total revenue	$ 19.3	$ 16.4	$ 2.9

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3873

Samsung Bioepis Exhibit 1017, pg. 3873

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of $105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104).

Sanofi-aventis Contract Research & Development Revenue

(In millions)	Three months ended June 30, 2006	2005
Regeneron expense reimbursement	$ 11.8	$ 7.1
Recognition of deferred revenue related to up-front payments	3.0	2.3
Total	$ 14.8	$ 9.4

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses increased in the second quarter of 2006 from the same period in 2005, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in the second quarter of 2006 from the same period in 2005, due to our January 2006 receipt of a $25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan. As of June 30, 2006, $75.2 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract research and development revenue earned from Procter & Gamble decreased in the second quarter of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

Contract manufacturing revenue relates to our long-term agreement with Merck & Co., Inc., which expires in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Contract manufacturing revenue increased in the second quarter of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Revenue and the related manufacturing expense are recognized as product is shipped, after acceptance by Merck. Included in contract manufacturing revenue in the second quarter of 2006 and 2005 were $0.4 million and $0.3 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. As of June 30, 2006, the remaining deferred balance of Merck's capital improvement reimbursements totaled $0.4 million, which will be recognized as revenue as product is shipped based upon Merck's order quantities through October 2006.

Expenses:

Total operating expenses decreased to $43.5 million in the second quarter of 2006 from $48.5 million in the same period of 2005, due, in part, to our lower headcount. Our average headcount declined to 583 in the second quarter of 2006 from 731 in the same period of 2005 primarily as a

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3874

Samsung Bioepis Exhibit 1017, pg. 3874

result of workforce reductions made in the fourth quarter of 2005. (See "Severance Costs" below.)

Operating expenses in the second quarter of 2006 and 2005 include a total of $4.6 million and $5.3 million of Stock Option Expense, respectively, as detailed below:

(In millions)	For the three months ended June 30, 2006		
Expenses	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 31.8	$ 2.6	$ 34.4
Contract manufacturing	2.7	0.1	2.8
General and administrative	4.4	1.9	6.3
Total operating expenses	$ 38.9	$ 4.6	$ 43.5

(In millions)	For the three months ended June 30, 2005		
Expenses	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 37.3	$ 3.3	$ 40.6
Contract manufacturing	1.6	0.1	1.7
General and administrative	4.3	1.9	6.2
Total operating expenses	$ 43.2	$ 5.3	$ 48.5

Research and Development Expenses:

Research and development expenses decreased to $34.4 million in the second quarter of 2006 from $40.6 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2006 and 2005:

(In millions)	Three months ended June 30,		
Research and development expenses	2006	2005	Increase (Decrease)
Payroll and benefits (1)	$ 11.7	$ 14.0	$ (2.3)
Clinical trial expenses	4.4	6.4	(2.0)
Clinical manufacturing costs (2)	9.1	8.2	0.9
Research and preclinical development costs	4.3	5.8	(1.5)
Occupancy and other operating costs	4.9	6.2	(1.3)
Total research and development	$ 34.4	$ 40.6	$ (6.2)

(1) Includes $2.2 million and $2.9 million of Stock Option Expense for the three months ended June 30, 2006 and 2005, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.4 million of Stock Option Expense for both the three months ended June 30, 2006 and 2005.

Payroll and benefits decreased principally due to our lower headcount in the second quarter of 2006, as described above. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006, as we discontinued clinical development of IL-1 Trap in adult rheumatoid arthritis

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3875

Samsung Bioepis Exhibit 1017, pg. 3875

and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs as we initiated a phase 2 clinical trial in wet AMD. Clinical manufacturing costs increased because of higher costs in 2006 related to manufacturing VEGF Trap clinical supplies, which were partially offset by lower costs related to manufacturing IL-1 Trap clinical supplies. Research and preclinical development costs decreased primarily because of our lower 2006 headcount and lower preclinical IL-1 Trap development costs in 2006. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to $2.8 million in the second quarter of 2006 from $1.7 million in the comparable quarter of 2005 primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses increased to $6.3 million in the second quarter of 2006 from $6.2 million in the same period of 2005 as higher administrative personnel-related costs were offset primarily by lower facility-related expenses and consulting costs in the second quarter of 2006.

Other Income and Expense:

In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble agreed to make a one-time $5.6 million payment to us, which we recognized as other contract income in the second quarter of 2005.

Investment income increased to $3.7 million in the second quarter of 2006 from $2.5 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was $3.0 million in the second quarter of 2006 and 2005. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Six Months Ended June 30, 2006 and 2005

Net Loss:

Regeneron reported a net loss of $44.0 million, or $0.77 per share (basic and diluted), for the first half of 2006 compared to a net loss of $31.1 million, or $0.56 per share (basic and diluted), for the same period of 2005. Results for the first half of 2005 included a $25.0 million one-time, non-recurring payment from sanofi-aventis, which was recognized as other contract income, in connection with the January 2005 amendment to our collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap-Eye.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3876

Samsung Bioepis Exhibit 1017, pg. 3876

Revenues:

Revenues for the six months ended June 30, 2006 and 2005 consist of the following:

(In millions)	2006	2005	Increase (Decrease)
Contract research & development revenue			
The sanofi-aventis Group	$ 28.7	$ 19.2	$ 9.5
The Procter & Gamble Company	—	6.0	(6.0)
Other	0.9	1.9	(1.0)
Total contract research & development revenue	29.6	27.1	2.5
Contract manufacturing revenue	7.9	5.5	2.4
Total revenue	$ 37.5	$ 32.6	$ 4.9

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of $105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with SAB 104.

Sanofi-aventis Contract Research & Development Revenue

(In millions)	Six months ended June 30, 2006	2005
Regeneron expense reimbursement	$ 22.6	$ 14.5
Recognition of deferred revenue related to up-front payments	6.1	4.7
Total	$ 28.7	$ 19.2

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses increased in the first half of 2006 from the same period in 2005, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in the first half of 2006 from the same period in 2005, due to our January 2006 receipt of a $25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

Contract research and development revenue earned from Procter & Gamble decreased in the first half of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

Contract manufacturing revenue increased in the first half of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Included in contract manufacturing revenue in the first half of 2006 and 2005 were $0.8 million and $0.6 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3877

Samsung Bioepis Exhibit 1017, pg. 3877

Expenses:

Total operating expenses decreased to $83.4 million in the first half of 2006 from $93.1 million in the same period of 2005, due, in part, to our lower headcount, as previously described above. (Also see "Severance Costs" below.)

Operating expenses in the first half of 2006 and 2005 include a total of $8.5 million and $10.7 million of Stock Option Expense, respectively, as detailed below:

(In millions)	**For the six months ended June 30, 2006**		
Expenses	**Expenses before inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
Research and development	$ 61.9	$ 4.6	$ 66.5
Contract manufacturing	4.5	0.2	4.7
General and administrative	8.5	3.7	12.2
Total operating expenses	$ 74.9	$ 8.5	$ 83.4

(In millions)	**For the six months ended June 30, 2005**		
Expenses	**Expenses before inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
Research and development	$ 69.8	$ 6.7	$ 76.5
Contract manufacturing	4.1	0.1	4.2
General and administrative	8.5	3.9	12.4
Total operating expenses	$ 82.4	$ 10.7	$ 93.1

Research and Development Expenses:

Research and development expenses decreased to $66.5 million in the second half of 2006 from $76.5 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2006 and 2005:

(In millions)	**Six months ended June 30,**		
Research and development expenses	**2006**	**2005**	**Increase (Decrease)**
Payroll and benefits (1)	$ 21.7	$ 28.4	$ (6.7)
Clinical trial expenses	7.8	8.5	(0.7)
Clinical manufacturing costs (2)	18.4	17.3	1.1
Research and preclinical development costs	7.8	10.7	(2.9)
Occupancy and other operating costs	10.8	11.6	(0.8)
Total research and development	$ 66.5	$ 76.5	$ (10.0)

(1) Includes $3.8 million and $5.9 million of Stock Option Expense for the six months ended June 30, 2006 and 2005, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.7 million and $0.8 million of Stock Option Expense for the six months ended June 30, 2006 and 2005, respectively.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3878

Samsung Bioepis Exhibit 1017, pg. 3878

Payroll and benefits decreased principally due to our lower headcount in the first half of 2006. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006 as we discontinued clinical development of IL-1 Trap in adult rheumatoid arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs primarily in connection with initiating a phase 2 clinical trial in wet AMD. Clinical manufacturing costs increased because of higher costs in 2006 related to manufacturing VEGF Trap clinical supplies, which were partially offset by lower costs related to manufacturing IL-1 Trap clinical supplies. Research and preclinical development costs decreased primarily because of our lower 2006 headcount and lower preclinical IL-1 Trap development costs in 2006. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount offset, in part, by higher costs for utilities in 2006.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to $4.7 million in the first half of 2006 from $4.2 million in the comparable period of 2005 primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses decreased to $12.2 million in the first half of 2006 from $12.4 million in the same period of 2005. In 2006, lower facility-related expenses and consulting costs were partly offset by higher patent-related and administrative personnel-related expenses.

Other Income and Expense:

As described above, in January 2005 we received a one-time $25.0 million payment from sanofi-aventis, which was recognized as other contract income in the first half of 2005. In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble agreed to make a one-time $5.6 million payment to us, which we recognized as other contract income in the first half of 2005.

Investment income increased to $7.2 million in the first half of 2006 from $4.8 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was $6.0 million in the first half of 2006 and 2005. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis and Merck, and investment income.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3879

Samsung Bioepis Exhibit 1017, pg. 3879

Six Months Ended June 30, 2006 and 2005

Cash (Used in) Provided by Operations:

At June 30, 2006, we had $304.1 million in cash, cash equivalents, and marketable securities compared with $316.7 million at December 31, 2005. In January 2006, we received a $25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

In the first half of 2006, our net loss was $44.0 million; however, cash used in our operations was only $15.4 million, principally because the above-described $25.0 million payment from sanofi-aventis was receivable at December 31, 2005 and paid in January 2006. In the first half of 2005, our net loss was $31.1 million; however, cash provided by our operations was $4.5 million, principally due to receipts during this period from the sanofi-aventis Group for (i) reimbursement of VEGF Trap development expenses incurred by us and (ii) a $25.0 million clinical milestone payment earned in December 2004.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was $58.4 million in the first half of 2006 compared to net cash provided by investing activities of $44.4 million in the same period in 2005, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first half of 2006, purchases of marketable securities exceeded sales or maturities by $57.4 million, whereas in the first half of 2005, sales or maturities of marketable securities exceeded purchases by $47.3 million.

Cash Provided by Financing Activities:

Cash provided by financing activities increased to $4.2 million in the first half of 2006 from $1.0 million in the same period in 2005 due primarily to an increase in issuances of Common Stock in connection with exercises of stock options.

The sanofi-aventis Group Agreement:

Under our collaboration agreement with sanofi-aventis, agreed upon worldwide VEGF Trap development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of a VEGF Trap product for intraocular delivery to the eye predates the first commercial sale of a VEGF Trap product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to $7.5 million of VEGF Trap development expenses in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3880

Samsung Bioepis Exhibit 1017, pg. 3880

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of VEGF Trap development expenses will terminate and we will retain all rights to the VEGF Trap.

Severance Costs:

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of our collaboration with Procter & Gamble, and the expected completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005, with the remainder planned for 2006 following the completion of our contract manufacturing activities for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included $0.2 million of non-cash expenses. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and are being expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. We estimate that total costs associated with the 2005 and planned 2006 workforce reductions will approximate $2.6 million, of which $2.2 million was charged to expense in the fourth quarter of 2005 and $0.4 million was charged to expense in the first half of 2006. We anticipate cost savings of approximately $8 million in 2006 resulting from the implementation of our workforce reduction.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $1.0 million and $3.8 million for the first half of 2006 and 2005, respectively. During the remainder of 2006, we expect to incur approximately $2 million to $4 million in capital expenditures which will primarily consist of equipment for our manufacturing, research, and development activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from sanofi-aventis, we currently anticipate that approximately 55%-65% of our expenditures for 2006 will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap; approximately 20%-25% of our expenditures for 2006 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2006 will be used for capital expenditures and general corporate purposes.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3881

Samsung Bioepis Exhibit 1017, pg. 3881

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaboration with sanofi-aventis. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least mid-2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of June 30, 2006, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In January 2005, we filed a shelf registration statement on Form S-3 to sell, in one or more offerings, up to $200.0 million of equity or debt securities, together or separately, which registration statement was declared effective in February 2005. However, there is no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

During the six months ended June 30, 2006, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2005.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3882

Samsung Bioepis Exhibit 1017, pg. 3882

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in an approximately $0.9 million and $1.1 million change in the fair market value of our investment portfolio at June 30, 2006 and 2005, respectively. The decrease in the impact of an interest rate change at June 30, 2006, compared to June 30, 2005, is due to decreases in our investment portfolio's balance and duration to maturity at the end of June 2006 versus the end of June 2005.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3883

Samsung Bioepis Exhibit 1017, pg. 3883

uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2005 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through June 30, 2006, we had a cumulative loss of $629.2 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We currently receive contract manufacturing revenue from our agreement with Merck and, until June 30, 2005, we received contract research and development revenue from our agreement with The Procter & Gamble Company. Our agreement with Procter & Gamble expired in June 2005 and our agreement with Merck will expire before the end of 2006. The expiration of these agreements results in a significant loss of revenue to the Company.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least mid-2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3884

Samsung Bioepis Exhibit 1017, pg. 3884

2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3885

Samsung Bioepis Exhibit 1017, pg. 3885

of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of the IL-1 Trap in different diseases after a phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate (s), and our business, financial condition, and results of operations may be materially harmed.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions, referred to as infusion reactions. These and other

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3886

Samsung Bioepis Exhibit 1017, pg. 3886

complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

Although the IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events in the phase 2 rheumatoid arthritis study completed in 2003, safety or tolerability concerns may arise as we test higher doses of the IL-1 Trap in patients with other inflammatory diseases and disorders. Like TNF-antagonists such as Enbrel® (Amgen) and Remicade® (Centocor), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, there may be an increased risk for infections to develop in patients treated with the IL-1 Trap. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the IL-1 Trap.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date — in some cases even after pivotal clinical trials have been completed. Subjects who received the IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap develop antibodies to the product candidate.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3887

Samsung Bioepis Exhibit 1017, pg. 3887

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap or VEGF Trap-Eye or in a damage award.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3888

Samsung Bioepis Exhibit 1017, pg. 3888

prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3889

Samsung Bioepis Exhibit 1017, pg. 3889

The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2005, which report was included in our Annual Report on Form 10-K for the year ended December 31, 2005. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3890

Samsung Bioepis Exhibit 1017, pg. 3890

commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regnlatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regnlatory compliance, the FDA can impose regnlatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3891

Samsung Bioepis Exhibit 1017, pg. 3891

with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. Under a long-term manufacturing agreement with Merck, which expires in October 2006, we produce an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. We also use our facilities to produce API for our own clinical and preclinical candidates. When we no longer use our facilities to manufacture the Merck intermediate or if clinical candidates are discontinued, we will have to absorb overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3892

Samsung Bioepis Exhibit 1017, pg. 3892

these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote siguificant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Onyx Pharmaceuticals and Bayer have received approval from the FDA to market and sell the first oral medication that targets tumor cell growth and new vasculature

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3893

Samsung Bioepis Exhibit 1017, pg. 3893

formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the Onyx/Bayer kinase inhibitor, because doctors and patients will have siguificant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye diseases is also very competitive. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor (Macugen®) for age-related macular degeneration (wet AMD). Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis™) for the treatment of wet AMD and other eye indications that was approved by the FDA in June 2006. In addition, it has been reported that ophthalmologists are using a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The marketing approval of Macugen and Lucentis and the potential off-label use of Avastin make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis or Macugen, because doctors and patients will have significant experience using these medicines. Moreover, the relatively low cost of therapy with Avastin in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Amgen), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have siguificant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Novartis is developing an antibody to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3894

Samsung Bioepis Exhibit 1017, pg. 3894

We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the *CIAS*1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers.

Sales of biopharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payers, the market for any biopharmaceutical product will be limited. These third-party payers increasingly challenge the price and examine the cost-effectiveness of products and services. Significant uncertainty exists as to the reimbursement status of any new therapeutic, particularly if there exist lower-cost standards of care. Third-party payers may not reimburse sales of our products, which would harm our business.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, Murray A. Goldberg, our Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, Neil Stahl, Ph.D., our Senior Vice President, Preclinical Development and Biomolecular Science, and Randall G. Rupp, Ph.D., our Senior Vice President, Manufacturing Operations. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3895

Samsung Bioepis Exhibit 1017, pg. 3895

- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of April 13, 2006, our seven largest shareholders, including sanofi-aventis, beneficially owned 47.9% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 13, 2006. As of April 13, 2006, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 5.1% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, through September 5, 2006, sanofi-aventis may sell no more than 250,000 of these shares in any calendar quarter. After September 5, 2006, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 13, 2006, holders of Class A Stock held 4.1% of all shares of Common Stock and Class A Stock then outstanding, and had 29.7% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 13, 2006:

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3896

Samsung Bioepis Exhibit 1017, pg. 3896

- our current officers and directors beneficially owned 14.6% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2006, and 33.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2006; and
- our seven largest shareholders beneficially owned 47.9% of our outstanding shares of Common Stock assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 13, 2006. In addition, these seven shareholders held 54.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of April 13, 2006.

The anti-takeover effects of provisions of our charter, by-laws, and rights agreement, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws, our rights agreement and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3897

Samsung Bioepis Exhibit 1017, pg. 3897

- under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

We have a shareholder rights plan which could make it more difficult for a third party to acquire us without the support of our board of directors and principal shareholders. In addition, many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of the Company, as defined in the plan.

Item 4. Submission of Matters to a Vote of Security Holders

On June 9, 2006, we conducted our Annual Meeting of Shareholders pursuant to due notice. A quorum being present either in person or by proxy, the shareholders voted on the following matters:

1. To elect four Directors to hold office for a three-year term as Class III directors, and until their successors are duly elected and qualified.

2. To ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for our fiscal year ending December 31, 2006.

No other matters were voted on. The number of votes cast was:

	For	Withheld
1. Election of Class II Directors		
Charles A. Baker.	68,193,948	1,341,920
Michael S. Brown, M.D.	68,530,409	1,005,459
Arthur F. Ryan	68,681,939	853,929
George L. Sing	68,239,673	1,296,195

The terms of office of Leonard S. Schleifer, M.D., Ph.D., Eric M. Shooter, Ph.D., George D. Yancopoulos, M.D., Ph.D., Alfred G. Gilman, M.D., Ph.D., Joseph L. Goldstein, M.D., and P. Roy Vagelos, M.D. continued after the meeting.

	For	Against	Abstain
2. Ratification of the Appointment of Independent Registered Public Accounting Firm	69,093,166	105,312	337,390

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3898

Samsung Bioepis Exhibit 1017, pg. 3898

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
12.1	- Statement re: computation of ratio of earnings to combined fixed charges.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3899

Samsung Bioepis Exhibit 1017, pg. 3899

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: August 8, 2006

By: /s/ Murray A. Goldberg
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3900

Samsung Bioepis Exhibit 1017, pg. 3900

Exhibit 12.1

Regeneron Pharmaceuticals, Inc.
Computation of Ratio of Earnings to Combined Fixed Charges
(Dollars in thousands)

	Years ended December 31,					Six months ended June 30,
	2001	2002	2003	2004	2005	2006
Earnings:						
Income (loss) from continuing operations before income (loss) from equity investee	$(75,178)	$(124,350)	$(107,395)	$41,565	$(95,456)	(44,769)
Fixed charges	3,888	13,685	14,108	14,060	13,687	6,817
Amortization of capitalized interest	—	—	33	78	78	39
Interest capitalized	—	(222)	(276)	—	—	—
Adjusted earnings	$(71,290)	$(110,887)	$ (93,530)	$55,703	$(81,691)	$(37,913)
Fixed charges:						
Interest expense	$ 2,657	$ 11,859	$ 11,932	$12,175	$ 12,046	$ 6,022
Interest capitalized	—	222	276	—	—	—
Assumed interest component of rental charges	1,231	1,604	1,900	1,885	1,641	795
Total fixed charges	$ 3,888	$ 13,685	$ 14,108	$14,060	$ 13,687	$ 6,817
Ratio of earnings to fixed charges	(A)	(A)	(A)	3.96	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2001, 2002, 2003, and 2005, and for the six months ended June 30, 2006, the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

	Years ended December 31,				Six months ended June 30,
	2001	2002	2003	2005	2006
Coverage deficiency	$ 75,178	$124,572	$107,638	$ 95,378	$ 44,730

Exhibit 31.1

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2006

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 31.2

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2006

/s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance &
Administration, Chief Financial Officer,
Treasurer, and Assistant Secretary

Exhibit 32

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
August 8, 2006

/s/ Murray A. Goldberg

Murray A. Goldberg
Chief Financial Officer
August 8, 2006

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 11/6/2006

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2006

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of October 31, 2006:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,296,928
Common Stock, $0.001 par value	55,153,986

REGENERON PHARMACEUTICALS, INC.
Table of Contents
September 30, 2006

	Page Numbers
PART I FINANCIAL INFORMATION	
Item 1 Financial Statements	
Condensed balance sheets (unaudited) at September 30, 2006 and December 31, 2005	3
Condensed statements of operations (unaudited) for the three and nine months ended September 30, 2006 and 2005	4
Condensed statement of stockholders' equity (unaudited) for the nine months ended September 30, 2006	5
Condensed statements of cash flows (unaudited) for the nine months ended September 30, 2006 and 2005	6
Notes to condensed financial statements (unaudited)	7-20
Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations	21-42
Item 3 Quantitative & Qualitative Disclosure About Market Risk	42
Item 4 Controls and Procedures	42-43
PART II OTHER INFORMATION	
Item 1 Legal Proceedings	43
Item 1A Risk Factors	43-58
Item 6 Exhibits	59
SIGNATURE PAGE	60
EX-10.1: LICENSE AND COLLABORATION AGREEMENT	
EX-12.1: STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS TO COMBINED FIXED CHARGES	
EX-31.1: CERTIFICATION	
EX-31.2: CERTIFICATION	
EX-32: CERTIFICATION	

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2006 AND DECEMBER 31, 2005 (Unaudited)
(In thousands, except share data)

	September 30, 2006	December 31, 2005
ASSETS		
Current assets		
Cash and cash equivalents	$ 167,662	$ 184,508
Marketable securities	94,227	114,037
Accounts receivable	7,940	36,521
Prepaid expenses and other current assets	3,920	3,422
Inventory		2,904
Total current assets	273,749	341,392
Marketable securities	27,708	18,109
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	51,035	60,535
Other assets	2,694	3,465
Total assets	$ 355,186	$ 423,501
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 19,054	$ 23,337
Deferred revenue, current portion	13,644	17,020
Total current liabilities	32,698	40,357
Deferred revenue	60,015	69,142
Notes payable	200,000	200,000
Total liabilities	292,713	309,499
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,296,928 in 2006 and 2,347,073 in 2005	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 54,784,449 in 2006 and 54,092,268 in 2005	55	54
Additional paid-in capital	719,157	700,011
Unearned compensation		(315)
Accumulated deficit	(656,646)	(585,280)
Accumulated other comprehensive loss	(95)	(470)
Total stockholders' equity	62,473	114,002
Total liabilities and stockholders' equity	$ 355,186	$ 423,501

The accompanying notes are an integral part of the financial statements.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3910

Samsung Bioepis Exhibit 1017, pg. 3910

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30	
	2006	2005	2006	2005
Revenues				
Contract research and development	$ 11,448	$ 11,533	$ 41,026	$ 38,580
Contract manufacturing	4,176	4,661	12,075	10,189
	15,624	16,194	53,101	48,769
Expenses				
Research and development	34,808	41,116	101,290	117,670
Contract manufacturing	3,054	3,246	7,716	7,412
General and administrative	6,019	6,219	18,264	18,581
	43,881	50,581	127,270	143,663
Loss from operations	(28,257)	(34,387)	(74,169)	(94,894)
Other income (expense)				
Other contract income				30,640
Investment income	3,858	2,746	11,023	7,515
Interest expense	(3,011)	(3,011)	(9,033)	(9,035)
	847	(265)	1,990	29,120
Net loss before cumulative effect of a change in accounting principle	(27,410)	(34,652)	(72,179)	(65,774)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")			813	
Net loss	$ (27,410)	$ (34,652)	$ (71,366)	$ (65,774)
Net loss per share amounts, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	$ (0.48)	$ (0.62)	$ (1.27)	$ (1.18)
Cumulative effect of adopting SFAS 123R			0.02	
Net loss	$ (0.48)	$ (0.62)	$ (1.25)	$ (1.18)
Weighted average shares outstanding, basic and diluted	57,011	55,978	56,884	55,903

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 3911

Samsung Bioepis Exhibit 1017, pg. 3911