b. Attorneys' Fees. If either party commences an action against the other party arising out of or in connection with this Agreement, then the substantially prevailing party shall be reimbursed by the other party for all reasonable costs and expenses, including reasonable attorneys' fees and expenses, incurred by the substantially prevailing party in such action or proceeding and in any appeal in connection therewith.

c. Successors. This Agreement shall be binding on and inure to the benefit of the parties and their successors and assigns.

d. Counterparts. This Agreement may be executed in one or more counterparts that, when taken together, shall constitute one original.

e. Defined Terms. Capitalized terms not otherwise defined herein shall have the meanings given them in the Space License.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the day hereinabove first written.

OWNER:

BMR-LANDMARK AT EASTVIEW LLC,
a Delaware limited liability company

By: /s/ Kevin M. Simonsen
Name: Kevin M. Simonsen
Title: VP, Real Estate Counsel

USER:

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 10.2

NINTH AMENDMENT TO LEASE

THIS NINTH AMENDMENT TO LEASE (this "Amendment") is entered into as of this 30th day of September, 2011 (the "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, as amended by that certain First Amendment to Lease dated as of October 24, 2007, that certain Second Amendment to Lease dated as of September 30, 2008, that certain Third Amendment to Lease dated as of April 29, 2009, that certain Fourth Amendment to Lease dated as of December 3, 2009, that certain Fifth Amendment to Lease dated as of February 11, 2010, that certain Sixth Amendment to Lease dated as of June 4, 2010, that certain Seventh Amendment to Lease dated as of December 22, 2010, and that certain Eighth Amendment to Lease dated as of August 1, 2011 (collectively, and as the same may have been further amended, amended and restated, 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, Tenant desires to lease approximately thirty-nine thousand nine hundred fifty-four (39,954) rentable square feet of additional premises on the third (3rd) floor of the 777 Building, as depicted on Exhibit A attached hereto (the "01 Premises") and currently leased by another tenant ("Vacating Tenant");

C. 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 Amendment, capitalized terms shall have the meanings ascribed to them in the Lease unless otherwise defined herein. The Lease, as amended by this Amendment, is referred to herein as the "Amended Lease."

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2. Addition to Premises. Conditional upon Vacating Tenant surrendering the 01 Premises to Landlord in accordance with Vacating Tenant's lease, and subject to Tenant's termination options set forth in this Section and in Section 3 below, Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the 01 Premises as of the date (the "01 Premises Commencement Date") that is ten (10) days after Landlord notifies Tenant that Landlord has substantially completed the 01 Premises Landlord Improvements (as defined below). Effective as of the 01 Premises Commencement Date, the Premises shall include the 01 Premises. The Term for the 01 Premises 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 Lease and (b) Tenant's termination option set forth in this Section and in Section 3 below. If Vacating Tenant does not surrender the 01 Premises to Landlord by February 15, 2012, then Tenant may terminate this Amendment by providing written notice of such termination to Landlord on or before April 15, 2012. Tenant shall execute and deliver to Landlord written acknowledgment of the actual 01 Premises Commencement Date, if the same occurs, within ten (10) days after Tenant takes occupancy of the 01 Premises, in the form attached as Exhibit D hereto. Failure to execute and deliver such acknowledgment, however, shall not affect the 01 Premises Commencement Date or Landlord's or Tenant's liability hereunder.

3. Termination Option. In addition to the termination option reserved to Tenant under Section 2 above, Tenant shall be entitled to terminate the Amended Lease with respect to the 01 Premises as of December 31, 2015, or December 31, 2016; provided that (a) Tenant provides Landlord with no less than twelve (12) months' prior written notice and (b) if the termination is (i) December 31, 2015, Tenant pays to Landlord on or before such date an amount equal to Seven Hundred Twenty Thousand Eight Hundred Two and 75/100 Dollars ($720,802.75) (ii) December 31, 2016, Tenant pays to Landlord on or before such date an amount equal to Six Hundred Thirty-Six Thousand Two and 45/100 Dollars ($636,002.45). If Tenant timely exercises its option to terminate the Amended Lease with respect to the 01 Premises, then Tenant shall surrender the 01 Premises to Landlord on the applicable surrender date in the condition required by the Amended Lease for surrendering Premises upon the expiration or earlier termination thereof. Time is of the essence with respect to the exercise of the termination option granted in this Section.

4. 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 and 765 Elevator Lobby Premises, (f) each full floor of the 755 Premises, (g) the 765 Expansion Premises, (h) the 765 Expansion Premises II, (i) C-Level Storage Spaces, (j) the 777 License Area Premises and (k) the 01 Premises. 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, although Tenant's Options for the remaining Premises shall remain in full force and effect.

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5. Condition of 01 Premises. Except as provided in Section 6 below, Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the 01 Premises with respect to the suitability of the same for the conduct of Tenant's business. Tenant acknowledges that it is generally familiar with the condition of the 01 Premises and, 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, except that Landlord shall (a) remove all existing furniture from the 01 Premises and (b) perform the 01 Premises Landlord Improvements set forth on Exhibit B attached hereto in accordance with this Amendment. Tenant's taking possession of the 01 Premises, except as otherwise agreed to in writing by Landlord and Tenant, shall conclusively establish that the same were at such time in good, sanitary and satisfactory condition and repair. Notwithstanding the foregoing, Landlord shall endeavor to minimize the odor of hydraulic fluid in or around the elevators located nearest to the 01 Premises to a level consistent with those found in connection with the operation of a typical hydraulic elevator, as of the 01 Premises Commencement Date.

6. Improvements.

(a) Landlord shall perform the improvements set forth on Exhibit B attached hereto and Tenant shall perform the improvements set forth on Exhibit C attached hereto at Landlord's sole cost and expense (collectively, the "01 Premises Landlord Improvements"). If Landlord has not substantially completed the portion of the 01 Premises Landlord Improvements depicted on Exhibit B by April 1, 2012, then the 01 Premises Rent Commencement Date (as defined below) shall be extended by one (1) day for every day after April 1, 2012, that Landlord has not substantially completed the portion of the 01 Premises Landlord Improvements depicted on Exhibit B, except to the extent that the delay was caused by Tenant or its agents, employees or contractors, or by Governmental Authorities. If Landlord and Tenant cannot agree on whether Landlord has substantially completed the portion of 01 Premises Landlord Improvements depicted on Exhibit B or the items listed on the Punchlist generated by the parties pursuant to the protocol set forth under Section 4.3 of the Lease, then the written determination of the Neutral Architect shall govern, whose determination shall be final and binding upon the parties. For purposes of this Amendment, "substantially completed" means that Landlord has completed all of the 01 Premises Landlord Improvements depicted on Exhibit B, except for minor and insubstantial details of construction that do not, except in a de minimis manner, interfere with Tenant's performance of improvements to the Premises in accordance with this Section 6.

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(b) Landlord shall make available to Tenant a tenant improvement allowance of Five Hundred Ninety-Nine Thousand Three Hundred Ten Dollars ($599,310) (based on Fifteen Dollars ($15) per rentable square foot of the 01 Premises) (the "01 Premises Allowance") for Tenant's performance of its improvements (the "01 Premises Tenant Work"). In addition to the 01 Premises Allowance, Landlord shall also pay to Tenant an amount equal to the actual costs (the "Landlord Costs") incurred by Tenant for performing the portion of the 01 Premises Landlord Improvements set forth on Exhibit C attached hereto. The 01 Premises Allowance and the Landlord Costs shall be disbursed in the same manner as the Base TI Allowance under the applicable provisions of Article 5 of the Lease, including the Disbursement Conditions, in order to finance the aforesaid improvements to the 01 Premises. Tenant shall be responsible for performing and completing the 01 Premises Tenant Work and the 01 Premises Landlord Improvements set forth on Exhibit C attached hereto. Further, Tenant acknowledges and agrees that the scope of the 01 Premises Tenant Work shall be submitted, approved and constructed in accordance with the Work Letter attached as Exhibit G to the Lease and consistent with the provisions of the Amended Lease and the Permitted Use.

(c) In addition to the 01 Premises Allowance and the Landlord Costs referred to in Section 6(b) above, Landlord shall also make available to Tenant an additional allowance (the "Additional Allowance") of Three Hundred Fifty Thousand Dollars ($350,000) to pay for costs incurred by Tenant in excess of the 01 Premises Allowance in performing the 01 Premises Tenant Work, or any other Improvements elected to be performed by Tenant throughout the Term of the Lease to other areas of the Premises, all to be disbursed in the same manner as provided under Article 5 of the Lease, including the Disbursement Conditions; and to be submitted, approved and constructed in accordance with the Work Letter attached as Exhibit G to the Lease and consistent with the provisions of the Amended Lease and the Permitted Use.

(d) Tenant shall pay Landlord a construction oversight fee of two and one-half percent (2.5%) of the total cost of the 01 Premises Tenant Work or other improvements performed using the 01 Premises Allowance or the Additional Allowance, which construction oversight fee may be paid out of the 01 Premises Allowance or the Additional Allowance; provided, however, that Tenant shall not be required to pay such construction oversight fee for the portion of the 01 Premises Landlord Improvements depicted on Exhibit C attached hereto and performed by Tenant; and provided, further, that Tenant shall not be required to pay such construction oversight fee with respect to any portion of the Additional Allowance that is used to construct 01 Premises Tenant Work in the 01 Premises.

7. Early Access. Landlord shall grant Tenant access to the 01 Premises within five (5) business days after Vacating Tenant's surrender of the 01 Premises in order for Tenant to commence construction of the 01 Premises Landlord Improvements set forth on Exhibit C attached hereto and the 01 Premises Tenant Work. Landlord and Tenant shall reasonably cooperate with each other so as not to impede the other's work on the 01 Premises Landlord Improvements or 01 Premises Tenant Work, as applicable. In the event that Landlord does not permit Tenant such early access by January 15, 2012, the 01 Premises Rent Commencement Date (as defined below) shall be extended by two (2) days for every one (1) day of such delay, except to the extent that the delay was caused by Tenant or its agents, employees or contractors, or by delay caused by Governmental Authorities.

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8. Basic Annual Rent. Commencing as of the date that is twelve (12) months after the 01 Premises Commencement Date (the "01 Premises Rent Commencement Date") and continuing through the Term, but subject to the provisions of Section 3 hereof, Tenant shall pay to Landlord Basic Annual Rent for the 01 Premises at an initial rate equal to Twenty-Four and 50/100 Dollars ($24.50) per rentable square foot of the 01 Premises per year in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the 01 Premises shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent for the 01 Premises, commencing as of July 1, 2013.

9. Operating Expenses, Utilities and Basic Electric.

(a) In addition to Basic Annual Rent, commencing on the 01 Premises Commencement Date and continuing each month of the Term, Tenant shall also pay to Landlord, with respect to the 01 Premises, (i) Tenant's Pro-Rata Share of Operating Expenses that exceeds a calendar 2012 base year (grossed up to ninety-five percent (95%) occupancy) and (ii) Basic Electric Charges, all as set forth in the Lease.

(b) In the event that the Building or Project is less than fully occupied, Tenant acknowledges that Landlord may gross up Operating Expenses to ninety-five percent (95%) of the total rentable area of the Building or Project (as applicable). Tenant shall pay Tenant's proportionate share of the amount computed in accordance with the previous sentence, subject to adjustment as reasonably determined by Landlord; provided, however, that Landlord shall not recover more than one hundred percent (100%) of Operating Expenses.

10. Audits. Landlord and Tenant agree that Tenant's audits with respect to Landlord's annual operating statements for calendar years 2008 and 2009 are now complete and that no further amounts shall be charged or credited to Tenant based on such statements or audits.

11. Parking. The parties acknowledge that, in accordance with the Amended 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.

12. Broker. Tenant represents and warrants that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment, other than Studley ("Broker"), and agrees to indemnify, defend and hold Landlord 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 the making of this Amendment, and Landlord shall pay such commission to Broker pursuant to a separate agreement between Landlord and Broker.

13. No Default. Tenant represents, warrants and covenants that, to the best of Tenant's knowledge, Landlord and Tenant are not in default of any of their 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.

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14. Effect of Amendment. Except as modified by this 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 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 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 Amendment.

15. Miscellaneous. This Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Amendment are inserted and 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. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease, lease amendment or otherwise until execution by and delivery to both Landlord and Tenant.

16. Counterparts. This Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document.

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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 Amendment.

LANDLORD:

BMR-LANDMARK AT EASTVIEW LLC,
a Delaware limited liability company

By: /s/ John Bonanno
Name: John Bonanno
Title: Senior Vice President, Leasing and Development

TENANT:

REGENERON PHARMACEUTICALS, INC.,
a New York corporation

By: /s/ Joseph J. LaRosa
Name: Joseph J. LaRosa
Title: Senior Vice President, General Counsel and Secretary

EXHIBIT A

01 PREMISES

[IMAGE]

A-1

EXHIBIT B

01 PREMISES LANDLORD IMPROVEMENTS TO BE PERFORMED BY LANDLORD AT ITS COST

Landlord will develop engineered design documents ready for permit for all the 01 Premises Landlord Improvements described below, which drawings and specifications shall meet the requirements of the New York State building codes:

1. Landlord has recently upgraded portions of building management system to a system made by Johnson Controls International ("JCI System"); however, Landlord shall decommission any of the old existing base building management system and provide additional controls modifications and upgrades as required for the entire system to perform variable air volume operation with the JCI System controlling the air handling units and all variable air volume boxes. Landlord shall also provide Tenant viewable access to all equipment on the building management system serving its space and full control and access to all equipment on the building management system serving solely its space.

2. All existing supply fans shall have variable-frequency drives that will be used to modulate supply fan speed.

3. New variable-frequency drives will be provided for each return fan, and controlled to interlock with the matched supply fan. Final balancing of variable-frequency drives to align with tenant's variable air volume system on the floor shall be performed by tenant upon completion of tenant improvements.

4. Provide and install any sensors required to facilitate variable air volume supply air operation and control of the new return fan variable-frequency drives of the 01 Premises.

5. Design and install any additional controls required to keep the existing constant volume systems operating at constant air volume to serve the other spaces served by the air handling units as required (i.e., duct dampers, airflow sensors, etc.).

6. Landlord shall provide a minimum of 50,000 cubic feet per minute of HVAC capacity with adequate static pressure (1.5 cubic feet per minute per usable square foot) from air handlers that are new or recently refurbished.

7. If Landlord's air handling unit south 2 ("AHS-2") is one of the air handlers used to supply the dedicated 50,000 cubic feet per minute to the 01 Premises, AHS-2 shall be new or refurbished as necessary. Refurbishment would include new coils, control valves and coil trim, drain pans and condensate piping, and filter racks. The unit casing will be scraped and painted with epoxy paint, and any severe damage would be repaired with supplemental sheet metal. The entire case will be lined with perforated double wall acoustical lining.

   a. Heating, cooling and airflow capacity of the refurbished AHS-2 unit shall be equal to or more than 1.5 cubic feet per minute per rentable square foot.

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b. The existing supply fan wheel on AHS-2 will be removed and inspected and replaced if necessary.

c. The supply fan motor on AHS-2 will be tested and replaced if necessary. Replacement of the unit would provide a unit of the same size and cubic feet per minute capacity as the existing, with all new components.

8. Landlord will provide a base building domestic hot water service to the 01 Premises.

9. Landlord shall remove existing duct mounted humidifiers and reheat coils in the penthouse portion of the 01 Premises.

10. Reheat coils serving other portions of the Premises shall remain in place.

11. Landlord shall identify a location from which Tenant shall extend electric service to the 01 Premises. The power made available shall be sufficient to support new renovation.

12. The electric service shall be metered by the base building management system. Electric meters will be used to separate the power usage dedicated to the 01 Premises only and shall be installed by Landlord.

13. The existing medium pressure duct loop serving the 01 Premises shall be in good working condition.

14. Ductwork serving the perimeter up-blast grilles from the catwalk level will be abandoned, the plenums removed and the floor penetrations filled with fire rated construction meeting all code requirements.

15. Landlord shall fill the floor air distribution holes with an acceptable floor fill material and detail, and modify the existing conditions to adequately close and fire rate all perimeter slab penetrations including maintaining the asbestos management program for asbestos containing material located on the floor below.

16. Abandon existing below floor air distribution and infill existing slab penetrations with fire rating assembly.

17. Landlord will provide baseline balancing report and final balancing report upon completion of the 01 Premises Landlord Improvements detailing the heating, cooling and airflow capacity of each unit and forward the information to Tenant for Tenant's use.

18. One (1) air handling unit located on the catwalk level also serves the 01 Premises and shall remain: air handling unit 2B-5 provides air to the south exposure underfloor perimeter grilles.

19. Remove all existing humidifiers and reheat coils at the penthouse level for air handling units serving the 01 Premises.

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20. Provide new steam-to-hot water converters and infrastructure to provide hot water heating capacity for fit out of 1st and 2nd floors as required.

21. Provide airflow measuring station and automated damper to serve constant volume spaces to remain (areas outside project scope).

22. Provide new return fan variable-frequency drives for all three (3) existing air handling units.

23. Modify air handling unit programming for all three (3) units to allow for variable speed operation and return fan tracking.

24. Landlord shall ensure existing return air intakes located at building core are free and clear to support use of ceiling plenum as a return air plenum.

25. Fintube radiant control to be integrated into overhead ventilation control zone (variable air volume box).

26. Landlord shall provide 2-1/2" chilled water risers with valved and capped outlets for Tenant point of connection beyond demising wall. Tenant shall review Landlord's infrastructure changes to ensure that they meet Tenant's requirements. If supplemental air conditioning systems are required, they shall be provided by Tenant.

27. Landlord will provide or modify the hot water riser to extend down from the heat exchanger(s) in the penthouse to heat the space via perimeter fintube from the building hot water system.

28. Landlord shall design, permit and construct fire sprinkler service from the street or building to the 01 Level Premises. The main line shall be capped at the 01 Level Premises and be sized to accommodate ordinary fire hazard as required by the City of Greenburgh for office tenant improvements. Landlord will include the main line distribution to the 01 Level Premises, a control system and valves.

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EXHIBIT C

01 PREMISES LANDLORD IMPROVEMENTS TO BE PERFORMED BY TENANT AT LANDLORD'S COST

1. Purchase and install variable air volume boxes at a quantity of (1) every 1200 usable square feet (which equals 25 variable air volume boxes for the floor zones) plus 2 variable air volume boxes for conference rooms, 1 variable air volume box for the intermediate distribution frame, and 1 pantry variable air volume box, for a total of 29 variable air volume boxes. Variable air volume boxes over this quantity shall be provided by Tenant. The cost to provide and install the 29 variable air volume boxes will be determined by separate costs when bidding the construction work.

2. Tenant shall install a hot water loop to be used for the fintubes and fintube elements to heat the 01 Premises with perimeter hot water fintube.

3. All control valves shall be tied into the building management system and integrated into the variable air volume box controls by Tenant.

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EXHIBIT D

ACKNOWLEDGEMENT OF TERM COMMENCEMENT DATE
AND TERM EXPIRATION DATE

THIS ACKNOWLEDGEMENT OF TERM COMMENCEMENT DATE AND TERM EXPIRATION DATE is entered into as of September 1, 2011, with reference to 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"), that certain Sixth Amendment to Lease dated as of June 4, 2010 (the "Sixth Amendment"), that certain Seventh Amendment to Lease dated as of December 22, 2010 (the "Seventh Amendment"), that certain Eighth Amendment to Lease dated as of August 1, 2011 (the "Eighth Amendment") and that certain Ninth Amendment to Lease dated as of September 29, 2012 (the "Ninth Amendment" and, collectively with the Original Lease and the First Amendment, Second Amendment, Third Amendment, Fourth Amendment, Fifth Amendment, Sixth Amendment and Seventh Amendment, and as the same may have been further amended, supplemented or otherwise modified from time to time, the "Amended Lease"), by REGENERON PHARMACEUTICALS, INC., a New York corporation ("Tenant"), in favor of BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("Landlord"). All capitalized terms used herein without definition shall have the meanings ascribed to them in the Amended Lease.

Tenant hereby confirms the following:

1. Tenant accepted possession of the 01 Premises on [_____], 20[__].

2. The 01 Premises are in good order, condition and repair.

3. The 01 Premises Landlord Improvements are Substantially Complete.

4. All conditions of the Amended Lease with respect to the 01 Premises to be performed by Landlord as a condition to the full effectiveness of the Amended Lease have been satisfied, and Landlord has fulfilled all of its duties in the nature of inducements offered to Tenant to lease the 01 Premises.

5. In accordance with the provisions of Section 2 of the Ninth Amendment to the Amended Lease, the 01 Premises Commencement Date is [_____], 20[__], and, unless the Amended Lease is terminated prior to the Term Expiration Date pursuant to its terms, the Term Expiration Date shall be [_____], 20[__].

6. Tenant commenced occupancy of the 01 Premises for the Permitted Use on [_____], 20[__].

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7. The obligation to pay Rent is presently in effect and all Rent obligations on the part of Tenant under the Amended Lease with respect to the 01 Premises commenced to accrue on [_____], 20[__], with Basic Annual Rent for the 01 Premises payable on the dates and in amounts set forth in the Ninth Amendment.

8. The Amended Lease is in full force and effect, and the same represents the entire agreement between Landlord and Tenant concerning the Premises[, except [_____]].

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IN WITNESS WHEREOF, Tenant has executed this Acknowledgment of Term Commencement Date and Term Expiration Date as of the date first written above.

TENANT:

REGENERON PHARMACEUTICALS, INC.
a New York Corporation

By:
Name:
Title:

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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 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: October 27, 2011

/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 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: October 27, 2011

/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 September 30, 2011 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
October 27, 2011

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
October 27, 2011

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 5/2/2006

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934

Date of Report (Date of earliest event reported): May 2, 2006 (May 1, 2006)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**000-19034**	**133444607**
(State or other jurisdiction of incorporation)	(Commission File Number)	**(I.R.S. Employer Identification Number)**

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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EX-99.A: PRESS RELEASE

Item 7.01 Regulation FD Disclosure

On May 1, 2006, the Company issued a press release announcing positive preliminary results from its phase 1 trial of the Vascular Endothelial Growth Factor (VEGF) Trap in patients with the neovascular form of age-related macular degeneration. A copy of the press release is included as Exhibit 99(a) to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Press Release of Regeneron Pharmaceuticals, Inc. dated May 1, 2006.

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Dated: May 2, 2006

By: /s/ Stuart Kolinski
Stuart Kolinski
Vice President and General Counsel

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Number	Description
99(a)	Press Release of Regeneron Pharmaceuticals, Inc. dated May 1, 2006.

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Exhibit 99(a)

FOR IMMEDIATE RELEASE

REGENERON REPORTS POSITIVE PHASE 1 DATA FOR THE VEGF TRAP IN AGE-RELATED MACULAR DEGENERATION

Preliminary results show improvements in vision and retinal swelling

VEGF Trap was well tolerated at all dose levels

Company also announces initiation of phase 2 trial

Tarrytown, New York (May 1, 2006) – Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) announced today positive preliminary results from its phase 1 trial of the Vascular Endothelial Growth Factor (VEGF) Trap in patients with the neovascular form of age-related macular degeneration (wet AMD). In addition to meeting its primary endpoints of safety and tolerability at all dose levels, the VEGF Trap demonstrated positive preliminary efficacy results. Based on these encouraging data, the Company announced today the start of a phase 2 trial in wet AMD. The data from the phase 1 trial were presented today at the 2006 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting and are available on the Company's web site, www.regeneron.com.

"We are very encouraged both by the promising safety and tolerability data from this trial and by the observed improvements in both retinal swelling and visual acuity in patients following a single dose of this very high-affinity VEGF blocking agent," said George Yancopoulos, M.D., Ph.D., Regeneron's Executive Vice President, Chief Scientific Officer, and President, Regeneron Research Laboratories. "With the start of the phase 2 trial, we hope to validate these early, preliminary findings in a more comprehensive study, determine an optimal dosing regimen, and progress rapidly to registration studies for the VEGF Trap in wet AMD. In addition, we have initiated a small pilot study in patients with diabetic macular edema (DME)."

About the Phase 1 Study

A total of 21 patients with wet AMD received a single intravitreal injection of 0.05, 0.15, 0.5, 1, 2, or 4 milligrams (mg) of VEGF Trap. Patients were followed for 6 weeks at which time they were permitted, according to the study protocol, to receive other available treatments. The report presented at the ARVO meeting covers the initial 6-week evaluation phase of the trial, for which data is now available for all 21 patients. Preliminary results were as follows:

- Single doses of the VEGF Trap were generally well tolerated at all dose levels tested (0.05 to 4 mg), with no systemic or serious adverse events reported. Dose escalation to the highest planned dose was achieved without reaching a maximum tolerated dose (MTD).
- 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.
- The best corrected visual acuity (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 gaining 15 or more letters.
- There was a large, rapid and sustained decrease in retinal thickness as measured by ocular coherence tomography (OCT). As measured by posterior pole OCT scans, the median excess retinal thickness was 194 microns at baseline and 60 microns at 6 weeks; as assessed by the Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline and 27 microns at 6 weeks.

Phase 2 Trial

Based on the preliminary phase 1 results, the Company announced today the start of 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 using different doses and different dosing regimens, as well as safety and efficacy.

Additional Data to be Presented at ARVO

Listed below are the titles and presentation times for additional clinical and pre-clinical data that have been scheduled for presentation at ARVO:

- Pharmacokinetics and Ocular Tissue Penetration of VEGF Trap after Intravitreal Injection in Rabbits (May 1, 8:30 am)
- Pre-clinical Development of VEGF Trap for the Treatment of Neovascular Disease (May 1, 9:00 am)
- Safety Evaluation of Intravitreal Administration of VEGF Trap in Cynomolgus Monkeys for 13 Weeks (May 1, 11:15 am)
- Low Dose, Subconjunctival Administration of VEGF Trap Inhibits Suture-Induced Neovascularization and Inflammation (May 1, 11:15 am)

- Intravitreal Administration of VEGF Trap Suppresses Vascular Leak in the Retinas of Diabetic Rats (May 1, 11:15 am)
- Intravitreal Administration of VEGF Trap Inhibits Pathological Retinal Neovascularization in a Mouse Model of Oxygen-Induced Retinopathy (May 1, 11:15 am)
- Macular Edema: Lessons from Early Clinical Experiences (May 1, 1:15 pm)
- Histologic Evaluation of Laser-Induced Choroidal Neovascularization (CNV) in Primates Receiving Intravitreal Injections of VEGF Trap: Correlation with Florescein Angiography (May 1, 3:00 pm)
- A Double-Masked, Placebo-Controlled, Safety and Tolerabiltiy Study of Intravenous VEGF Trap in Patients with Diabetic Macular Edema (DME) (May 3, 8:30 am)
- Single Dll4 Allele Deletion Alters Retinal Vascular Development in Mice (May 3, 12:00 pm)

The VEGF Trap in Opthamalogy

Vascular endothelial growth factor (VEGF) is a naturally occurring protein in the body whose normal role is to trigger formation of new blood vessels (angiogenesis) to support the growth of the body's tissues and organs. It has also been associated with the abnormal growth and fragility of new blood vessels in the eye, which lead to the development of wet AMD. Other molecules that have been evaluated for treatment of wet AMD by blocking VEGF, including Macugen®, which has been approved by the US Food and Drug Administration, have demonstrated that blocking VEGF can result in stabilization or improvement of vision in patients with wet AMD. Wet AMD is the leading cause of vision loss and blindness in Americans aged 65 and over, with approximately 1.5 million people affected with this condition in the United States.

The VEGF Trap is a fully human, soluble VEGF receptor fusion protein that binds all forms of VEGF-A along with the related placental growth factor (PlGF). The VEGF Trap is designed to block the interaction of these growth factors with cell-surface receptors and prevent the subsequent formation of the new blood vessels that play an important role in the development of wet AMD.

About Regeneron Pharmaceuticals

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and

inflammatory diseases and has preclinical programs in other diseases and disorders.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreement with the sanofi-aventis Group, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2005. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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Contact
Lauren Tortorete
212.845.5609
ltortorete@biosector2.com

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 5/5/2006

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934

Date of Report (Date of earliest event reported): **May 4, 2006 (May 3, 2006)**

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**000-19034**	**133444607**
(State or other jurisdiction of incorporation)	(Commission File Number)	**(I.R.S. Employer Identification Number)**

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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EX-99.A: PRESS RELEASE

Item 2.02 Results of Operations and Financial Condition

On May 3, 2006, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter and three months ended March 31, 2006. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached hereto as Exhibit 99(a).

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Press Release of Regeneron Pharmaceuticals, Inc. dated May 3, 2006.

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Dated: May 4, 2006

By: /s/ Stuart Kolinski
Stuart Kolinski
Vice President and General Counsel

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Exhibit 99(a)

Regeneron Reports First Quarter Financial and Operating Results

TARRYTOWN, N.Y.—(BUSINESS WIRE)—Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial and operating results for the first quarter of 2006. The Company reported a net loss of $20.4 million, or $0.36 per share (basic and diluted) for the first quarter of 2006 compared with 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 the sanofi-aventis Group in connection with an amendment to the Company's collaboration agreement with sanofi-aventis, which was recognized as other contract income.

At March 31, 2006, cash and marketable securities totaled $324.2 million compared with $316.7 million at December 31, 2005. In January 2006, Regeneron received an up-front payment of $25.0 million from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration program to include Japan. The Company's $200.0 million of convertible notes, which bear interest at 5.5% per annum, mature in October 2008.

Current Business Highlights

In the first quarter of 2006, Regeneron continued to expand its broad-based clinical development program that is centered on product candidates in oncology, eye diseases, and inflammatory indications. In oncology, Regeneron's Vascular Endothelial Growth Factor (VEGF) Trap is being developed in collaboration with sanofi-aventis. The Company is independently developing the VEGF Trap-Eye, a specially purified and formulated form of the VEGF Trap for use in intraocular applications, and the Interleukin-1 (IL-1) Trap for certain inflammatory indications.

In the first quarter of 2006, Regeneron and sanofi-aventis initiated their phase 2 single-agent program for the VEGF Trap in cancer. Patient enrollment is underway in non-small cell lung adenocarcinoma (NSCLA), and two additional safety/efficacy studies in advanced ovarian cancer and symptomatic malignant ascites (SMA) are planned to begin shortly. In addition, the companies intend to conduct three trials evaluating the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens, the first of which is planned to begin in the second half of 2006. 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 other cancer trials in 2006.

In the clinical development program for the treatment of eye diseases, at the May 2006 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO),

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the Company reported positive preliminary results from its phase 1 trial of the VEGF Trap-Eye in patients with the neovascular form of age-related macular degeneration (wet AMD). A total of 21 patients received a single dose of VEGF Trap-Eye at doses ranging from .05 milligrams (mg) to 4 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 less than or equal to 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 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 gaining 15 or more letters.

Based on the preliminary phase 1 results in wet AMD, the Company has 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. The Company plans to conduct an initial evaluation of 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, Regeneron plans to initiate a phase 3 trial of the VEGF Trap in wet AMD in early 2007.

Regeneron recently completed enrollment in the pivotal study of the IL-1 Trap in patients with CIAS1-Associated Periodic Syndrome (CAPS), a spectrum of rare diseases associated with mutations in the CIAS1 gene. Interleukin-1 (IL-1) appears to play a significant role in these diseases. Participants in the trial will receive a 160 milligram dose of the IL-1 Trap once a week through subcutaneous self-administration. The six-month placebo-controlled, double-blind, efficacy phase is expected to be completed and preliminary data available by the end of 2006. The efficacy phase will be followed by a six-month open-label extension phase. In addition, Regeneron has ongoing proof-of-concept studies in other indications in which IL-1 may play a significant role, such as systemic juvenile idiopathic arthritis (SJIA). The Company has received Orphan Drug designation for the IL-1 Trap in CAPS and SJIA.

Financial Results

Regeneron's total revenue increased to $18.2 million in the first quarter of 2006 from $16.2 million in the same period of 2005 due to increases of $1.1 million in contract

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research and development revenue and $0.9 million in contract manufacturing revenue in the first quarter of 2006 from the same period of 2005. Contract research and development revenue in the first quarter of 2006 principally related to the Company's VEGF Trap collaboration with sanofi-aventis in cancer indications. In the first quarter of 2005, contract research and development revenue related both to the Company's collaboration with sanofi-aventis and the Company's collaboration with The Procter & Gamble Company, which ended in June 2005. Contract manufacturing revenue relates to Regeneron's long-term manufacturing agreement with Merck & Co., Inc., which will expire in the second half of 2006.

Regeneron recognized contract research and development revenue of $13.9 million in the first quarter of 2006 related to the Company's collaboration with sanofi-aventis, compared with $9.8 million in the same period of 2005. Contract research and development revenue from the sanofi-aventis collaboration consists of reimbursement of VEGF Trap development expenses plus recognition of amounts related to $105.0 million of previously received up-front, non-refundable payments. Reimbursement of expenses increased to $10.8 million in the first quarter of 2006 from $7.4 million in the same period of 2005, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. With respect to the up-front payments from sanofi-aventis, $3.1 million was recognized as revenue in the first quarter of 2006 compared to $2.4 million in the same quarter of 2005.

Sanofi-aventis also incurs VEGF Trap development expenses which are increasing because of the growing number of clinical trials sanofi-aventis is overseeing in the VEGF Trap oncology program. During the term of the collaboration, sanofi-aventis pays 100% of agreed-upon VEGF Trap development expenses incurred by both companies. Following commercialization of a VEGF Trap product by the collaboration, the Company will repay out of VEGF Trap profits 50% of these VEGF Trap development expenses previously paid by sanofi-aventis.

Total operating expenses for the first quarter of 2006 were $39.9 million, 10 percent lower than the same period in 2005, due, in part, to lower Company headcount. Average Company 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.

The Company recognized non-cash compensation expense related to employee stock option awards (Stock Option Expense) in accordance with Statement of Financial Accounting Standards No. (SFAS) 123 in 2005, and in accordance with SFAS 123R (which is a revision of SFAS 123), effective January 1, 2006. Operating expenses in the first quarter of 2006 and 2005 include a total of $3.9 million and $5.4 million, respectively of Stock Option Expense, as follows:

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For the three months ended March 31,

(in millions)	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

For the three months ended March 31,

(in millions)	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 (R&D) expenses decreased to $32.1 million in the first quarter of 2006 from $35.9 million in the comparable quarter of 2005. In addition to the impact of lower Company headcount, as described above, in the first quarter of 2006, the Company incurred lower development expenses for the IL-1 Trap and other clinical development programs, which were partly offset by higher development expenses for the VEGF Trap.

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 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 market value of share-based payments (including stock option awards) on their date of grant over the vesting period of the awards using the multiple-option approach. 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 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

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SFAS 123R adoption date. This adjustment reduced the Company's loss by $0.8 million and is included in the Company's operating results for the first quarter of 2006 as a cumulative-effect adjustment of a change in accounting principle.

About Regeneron Pharmaceuticals

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, and has preclinical programs in other diseases and disorders.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreement with the sanofi-aventis Group, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2005. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	March 31, 2006	December 31, 2005
ASSETS		
Cash and marketable securities	$ 324,229	$ 316,654
Receivables	11,010	36,521
Inventory	3,254	2,904
Property, plant, and equipment, net	57,421	60,535
Other assets	6,175	6,887
Total assets	$ 402,089	$ 423,501
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 18,383	$ 23,337
Deferred revenue	81,383	86,162
Notes payable	200,000	200,000
Stockholders' equity	102,323	114,002
Total liabilities and stockholders' equity	$ 402,089	$ 423,501

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REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the 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

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or
Media:
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212-845-5609
ltortorete@biosector2.com

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Samsung Bioepis Exhibit 1017, pg. 4852

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Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 6/9/2006

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934

Date of Report (Date of earliest event reported): June 9, 2006

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**000-19034**	**133444607**
(State or other jurisdiction of incorporation)	(Commission File Number)	**(I.R.S. Employer Identification Number)**

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 9.01 Financial Statements and Exhibits
Exhibit Index
EX-99.A: PRESENTATION SLIDES

Item 8.01 Other Events

On June 9, 2006, the Company presented the slides included as Exhibit 99(a) to this Current Report on Form 8-K at its Annual Meeting of Shareholders held at the Westchester Marriott Hotel, 670 White Plains Road, Tarrytown, New York. A copy of the slide presentation is also available on the Company's website at www.regneron.com.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Slides presented at the Company's 2006 Annual Meeting of Shareholders held on June 9, 2006.

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Dated: June 9, 2006

By: /s/ Stuart Kolinski
Stuart Kolinski
Vice President and General Counsel

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Exhibit Index

Number	Description
99(a)	Slides presented at the Company's 2006 Annual Meeting of Shareholders held on June 9, 2006.

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Regeneron Pharmaceuticals, Inc.

Annual Shareholders Meeting
June 9, 2006

Safe Harbor Statement

Except for historical information, the matters contained in this presentation may constitute forward-looking statements that involve risks and uncertainties, including uncertainties related to product development and clinical trials, unforeseen safety issues resulting from the administration of products in patients, uncertainties related to the need for regulatory and other government approvals, patents and proprietary technology, the need for additional capital, uncertainty of market acceptance of Regeneron's product candidates, the receipt of future payments, the continuation of business partnerships, and additional risks detailed from time to time in Regeneron's filings with the Securities and Exchange Commission (SEC). Please refer to Regeneron's recent Forms 10-K, 10-Q, and 8-K for additional information on the uncertainties and risk factors related to our business.

Because forward-looking statements involve risks and uncertainties, actual results may differ materially from current results expected by Regeneron. Regeneron is providing this information as of the original date of this presentation and expressly disclaims any duty to update any information contained in these materials.

REGENERON

Regeneron Overview

- 3 major clinical programs
  - Oncology
  - Eye Diseases
  - Inflammatory Diseases
- Major collaboration with sanofi-aventis
- Opportunity for additional collaborations including eye program and VelocImmune™
- Manufacturing expertise at 10,000 liter scale
- Next generation platform for monoclonal antibodies
- Strong financial position

REGENERON

Recent Progress

- Oncology
  - Three phase 2 single agent trials
  - Completing preparations for 3 Phase 3 combination studies
  - FDA submission targeted for 2007/2008 timeframe
- Eye diseases
  - Reported positive preliminary results in wet AMD
  - Phase 2 study underway
  - Phase 3 planned for initiation early 2007
  - Partnering opportunity
- IL-1 Trap – Inflammatory Diseases
  - Phase 3 pivotal study enrollment complete
  - Fast-track and orphan designation received from FDA
  - BLA submission targeted for 1H 2007
- Human monoclonal antibody platform
  - Source of new drug candidates and potential partnerships

REGENERON

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"Mechanism" vs. "Execution" Risk

- Mechanism Risk
  - Target not validated; no approved products with same molecular target
  - Mechanism-based toxicity ill-defined
  - Historically high rate of failure
- Execution Risk
  - Approved product validates molecular target and safety profile
  - Higher probability of successful development
  - 2nd and 3rd entries to "blockbuster" categories have history of strong commercial success

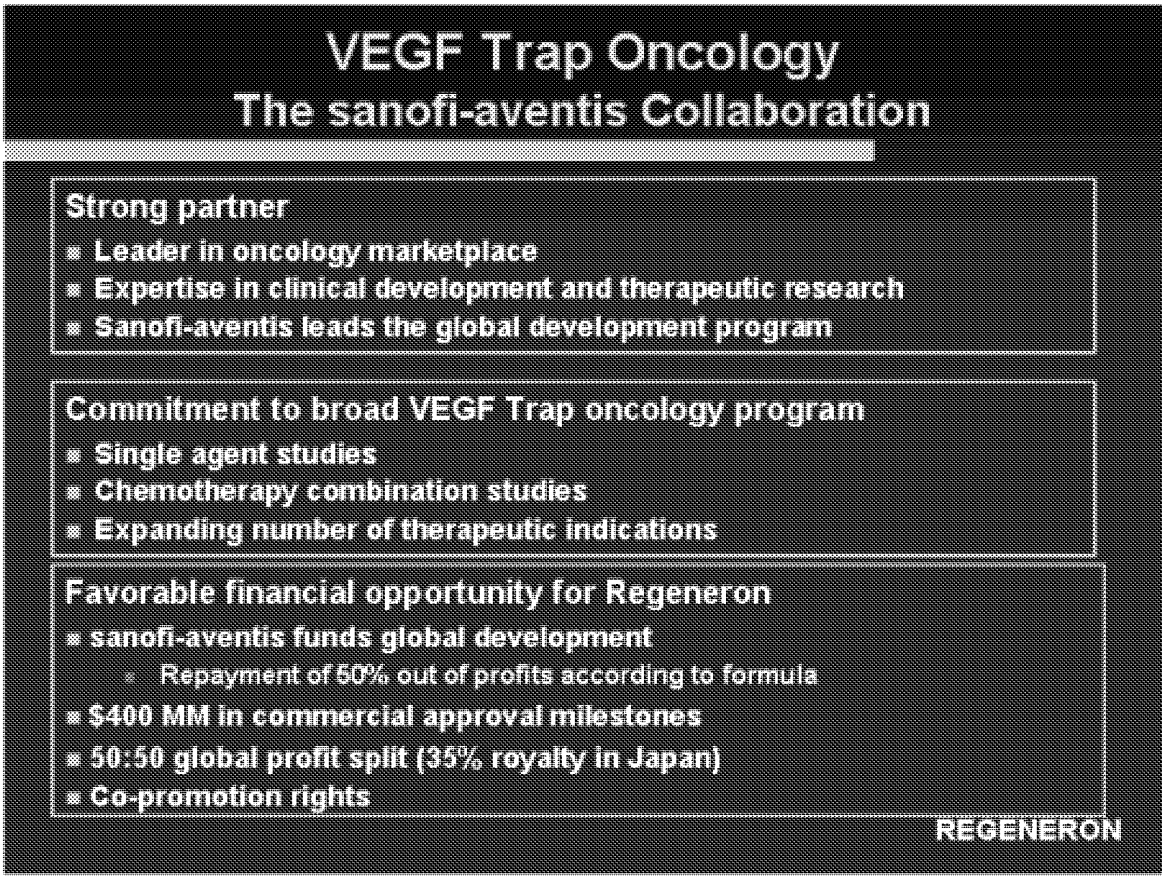
REGENERON

Regeneron Clinical Product Candidates

- Each candidate designed to address clinically validated target
- Each has opportunity to expand to new disease settings
- Clinical evidence already obtained indicating that each candidate addresses its target
- Regulatory approval strategy defined for each candidate

Execution vs. Mechanism Risk!

REGENERON


VEGF Trap Oncology
The sanofi-aventis Collaboration
Strong partner
» Leader in oncology marketplace
» Expertise in clinical development and therapeutic research
» Sanofi-aventis leads the global development program
Commitment to broad VEGF Trap oncology program
» Single agent studies
» Chemotherapy combination studies
» Expanding number of therapeutic indications
Favorable financial opportunity for Regeneron
» sanofi-aventis funds global development
» Repayment of 50% out of profits according to formula
» $400 MM in commercial approval milestones
» 50:50 global profit split (35% royalty in Japan)
» Co-promotion rights
REGENERON

Blocking VEGF with VEGF Trap

- **Clinical evidence that VEGF Trap can address "VEGF target"**
  - **Blood samples demonstrate "trapping" of VEGF**
  - **Decreased perfusion/vascular permeability after single dose**
  - **Adverse events of hypertension and proteinuria; expected based on Avastin® results**
  - **Responses observed in individual patients previously treated with multiple chemotherapy regimens**

REGENERON

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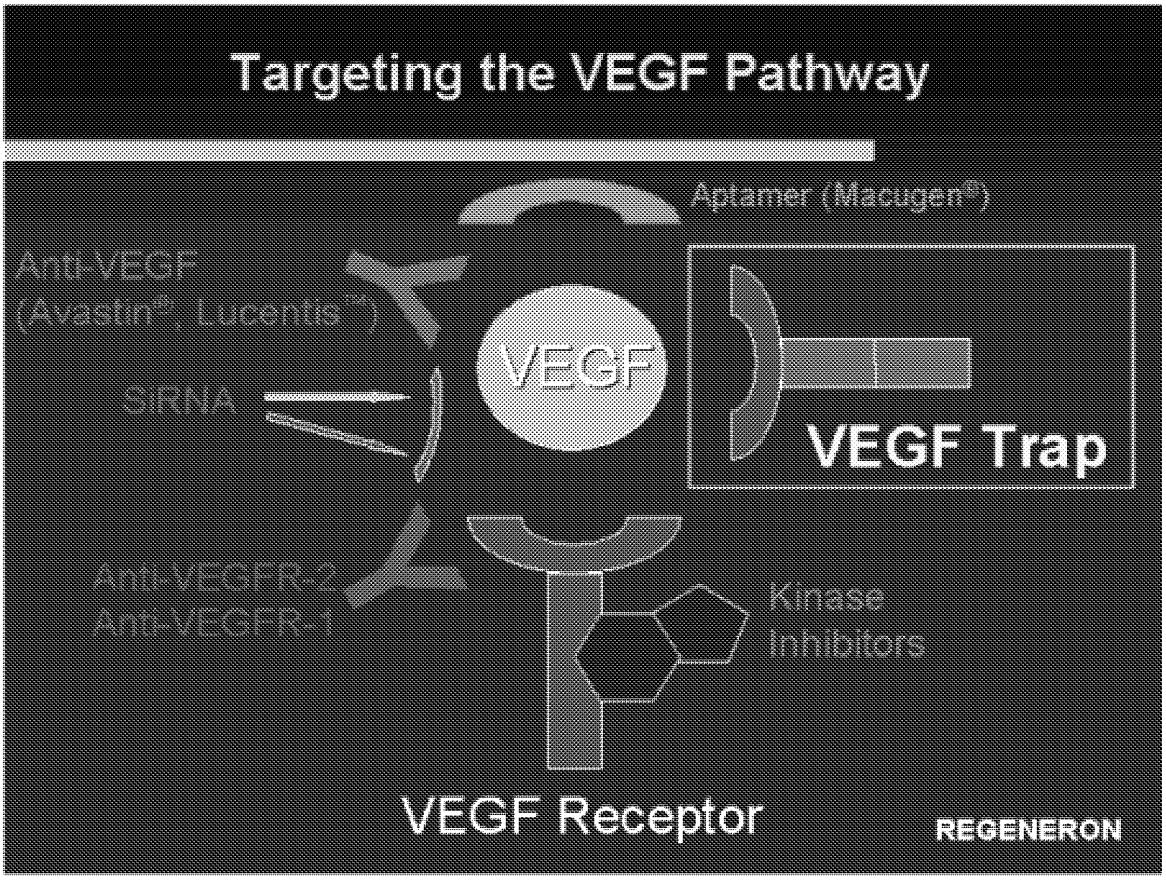
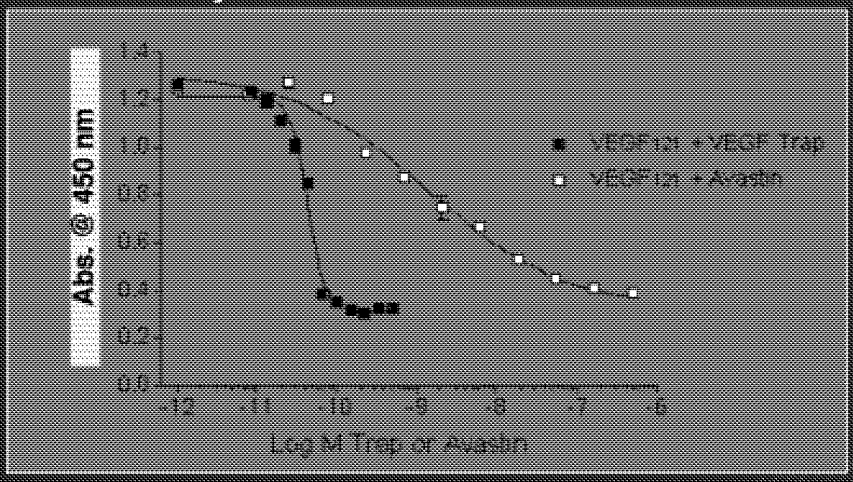

Targeting the VEGF Pathway
Aptamer (Macugen®)
Anti-VEGF
(Avastin®, Lucentis™)
SiRNA
VEGF
VEGF Trap
Anti-VEGFR-2
Anti-VEGFR-1
Kinase
Inhibitors
VEGF Receptor
REGENERON

Comparison of VEGF Trap and Avastin®

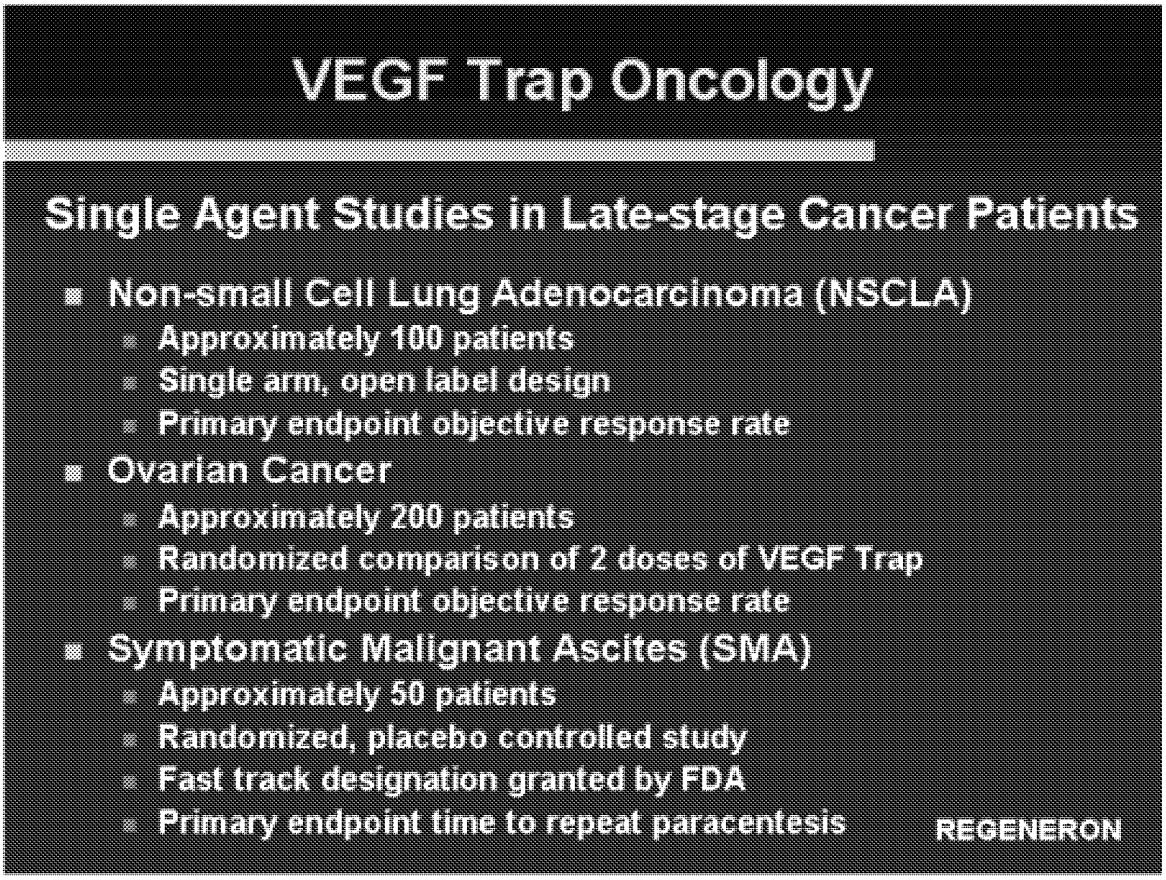
VEGF Trap has markedly higher affinity for VEGF than Avastin based on in vitro bioassay

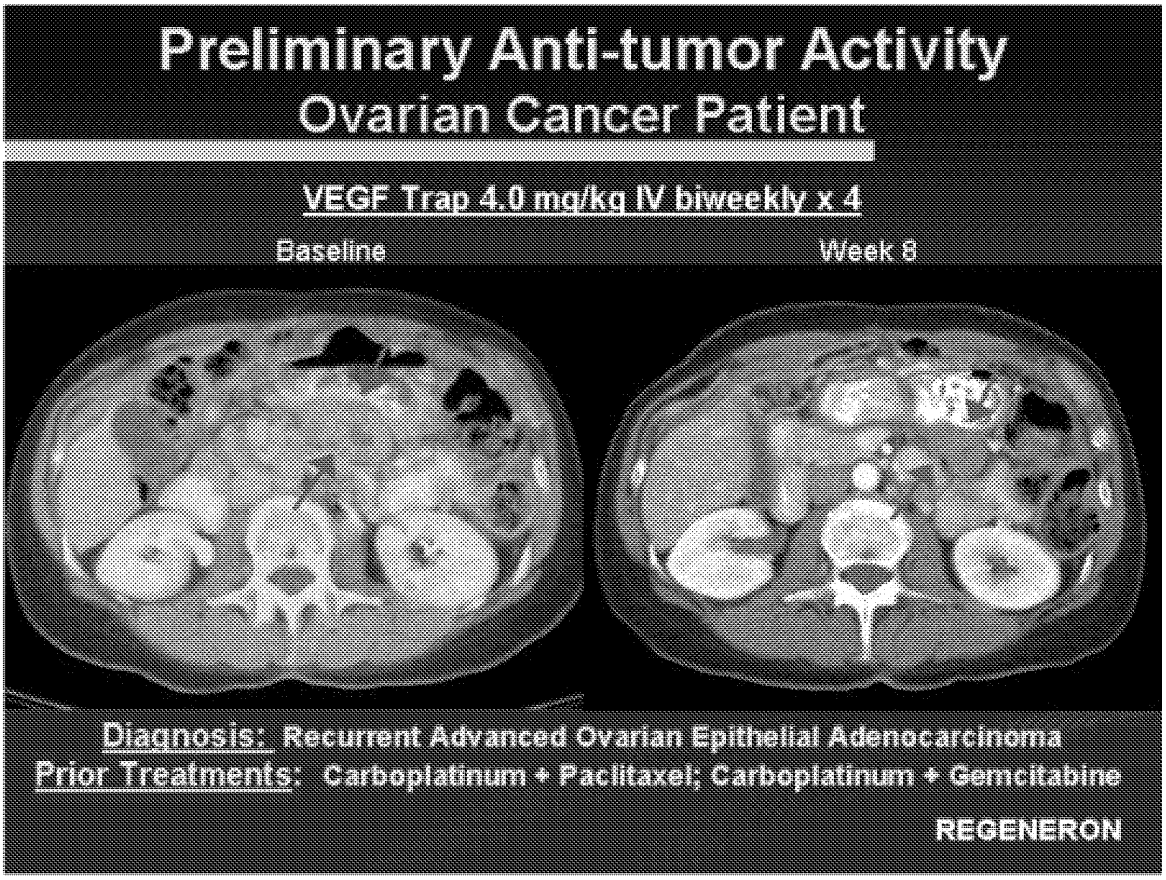


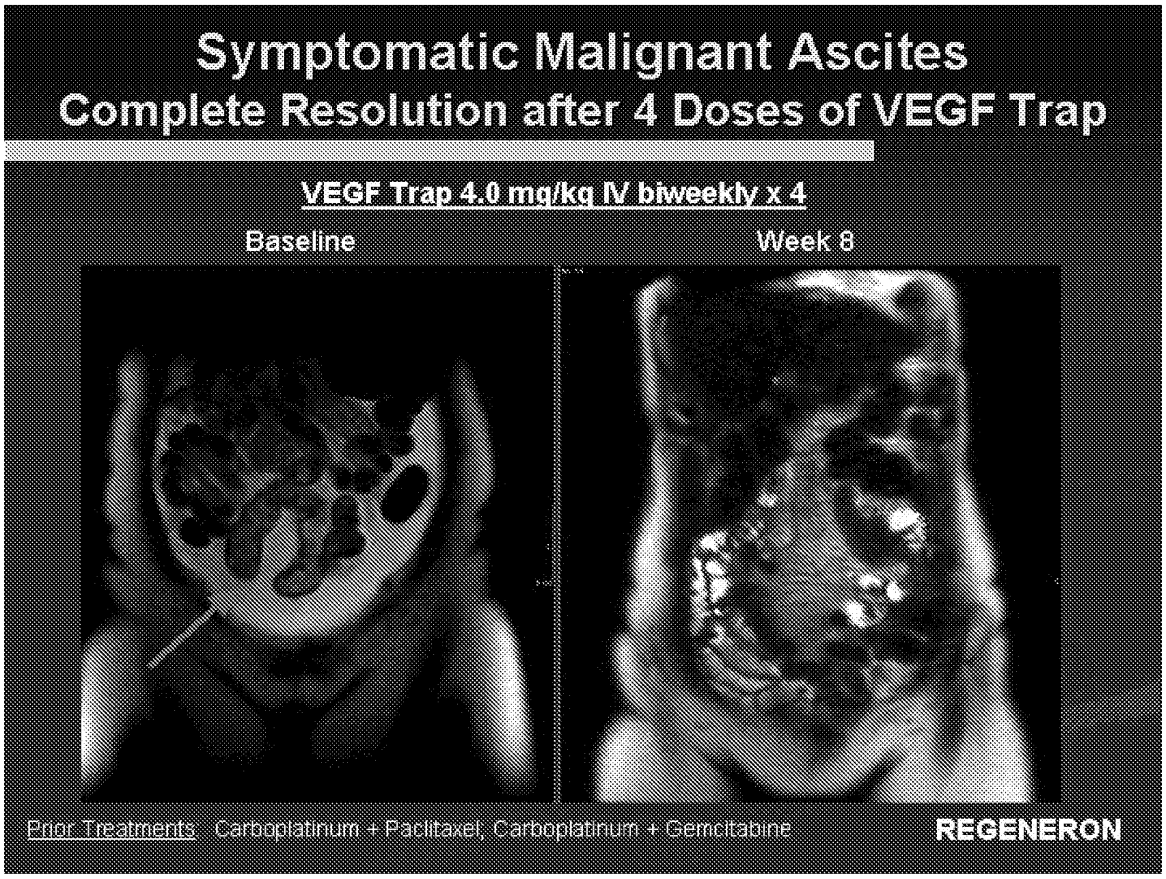
IC50 for VEGF Trap = 44pM

IC50 for Avastin = 1400pM

REGENERON


VEGF Trap Oncology
Single Agent Studies in Late-stage Cancer Patients
Non-small Cell Lung Adenocarcinoma (NSCLA)
Approximately 100 patients
Single arm, open label design
Primary endpoint objective response rate
Ovarian Cancer
Approximately 200 patients
Randomized comparison of 2 doses of VEGF Trap
Primary endpoint objective response rate
Symptomatic Malignant Ascites (SMA)
Approximately 50 patients
Randomized, placebo controlled study
Fast track designation granted by FDA
Primary endpoint time to repeat paracentesis
REGENERON


Preliminary Anti-tumor Activity
Ovarian Cancer Patient
VEGF Trap 4.0 mg/kg IV biweekly x 4
Baseline
Week 8
Diagnosis: Recurrent Advanced Ovarian Epithelial Adenocarcinoma
Prior Treatments: Carboplatinum + Paclitaxel; Carboplatinum + Gemcitabine
REGENERON


Symptomatic Malignant Ascites
Complete Resolution after 4 Doses of VEGF Trap
VEGF Trap 4.0 mg/kg IV biweekly x 4
Baseline
Week 8
Prior Treatments: Carboplatinum + Paclitaxel, Carboplatinum + Gemcitabine
REGENERON

VEGF Trap Oncology

VEGF Trap Studies in Combination with Standard Chemotherapy Regimens

- 5 phase 1b studies in different chemotherapy regimens
  - Encouraging early data with responses observed in heavily pretreated patients
- Phase 3 program to begin 2H 2006

REGENERON

VEGF Trap Oncology

VEGF Trap Studies being planned with National Cancer Institute

- National Cancer Institute to conduct trials of VEGF Trap under Clinical Trials Agreement between CTEP, NCI, and sanofi-aventis
- 10-12 efficacy/safety studies planned for 2006

REGENERON

VEGF Trap Oncology Summary

- VEGF confirmed as validated target
- Preliminary clinical evidence already obtained that VEGF Trap addresses target
- Clinical program being rapidly expanded
- Sanofi-aventis primary responsibility for execution of clinical trials
- First submission for approval planned for 2007/2008 timeframe

REGENERON

VEGF Trap Eye Program

- 100% owned by Regeneron
  - Partnering opportunity
- Initial target is neovascular form of age-related macular degeneration (wet AMD)
- Diabetic macular edema and diabetic proliferative retinopathy are additional commercial opportunities

REGENERON

Wet AMD: Current Landscape

- Macugen®: FDA approved aptamer that blocks long form of VEGF-A
  - Injections into the eye every 6 weeks
  - Slows down loss of vision
- Lucentis™: Antibody fragment that blocks all forms of VEGF-A
  - FDA Approval expected this month
  - Monthly injections into eye improves vision
  - Quarterly injections only maintain vision

REGENERON

Wet AMD: Opportunity

- Ability to give higher doses of more potent agent create opportunity for VEGF Trap-Eye program
- Goal is to prove that VEGF Trap is "best in class" by demonstrating in clinical trials:
  - More convenient dosing interval
  - Greater improvement of vision at optimal dosing interval

REGENERON

Phase 1 Intravitreal Trial

- Dose-ascending cohorts of 3-6 subjects given single intravitreal injection to determine maximum tolerated dose
- Primary endpoint safety and tolerability
  - Ocular coherence tomography (OCT) to assess retinal thickness
- Status and preliminary results
  - Dose levels of 0.05, 0.15, 0.5, 1.0, 2.0, and 4.0 mg
  - All planned dose levels completed: maximum tolerated dose not reached
  - Rapid, substantial, and prolonged (up to at least 6 weeks) reduction in retinal thickness demonstrated by OCT
  - Evidence for increased vision presented at ARVO 06

REGENERON

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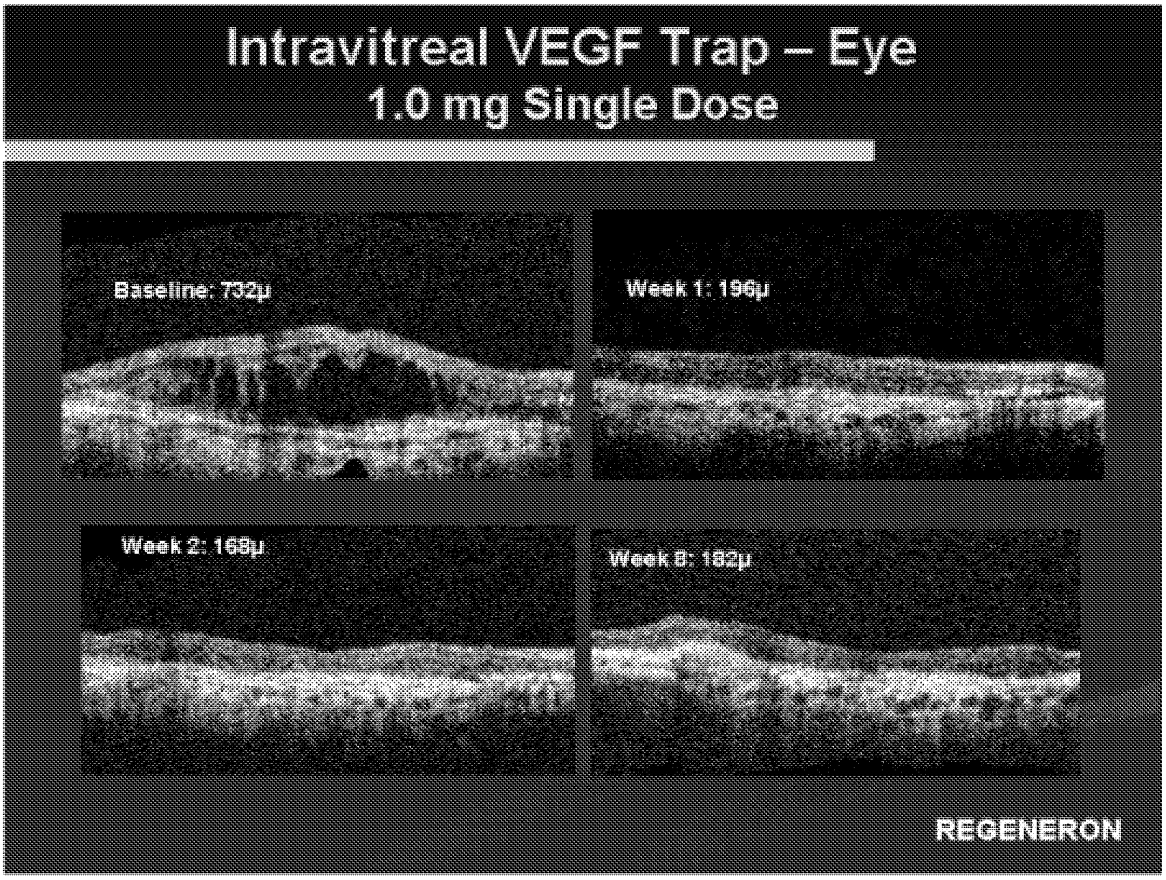
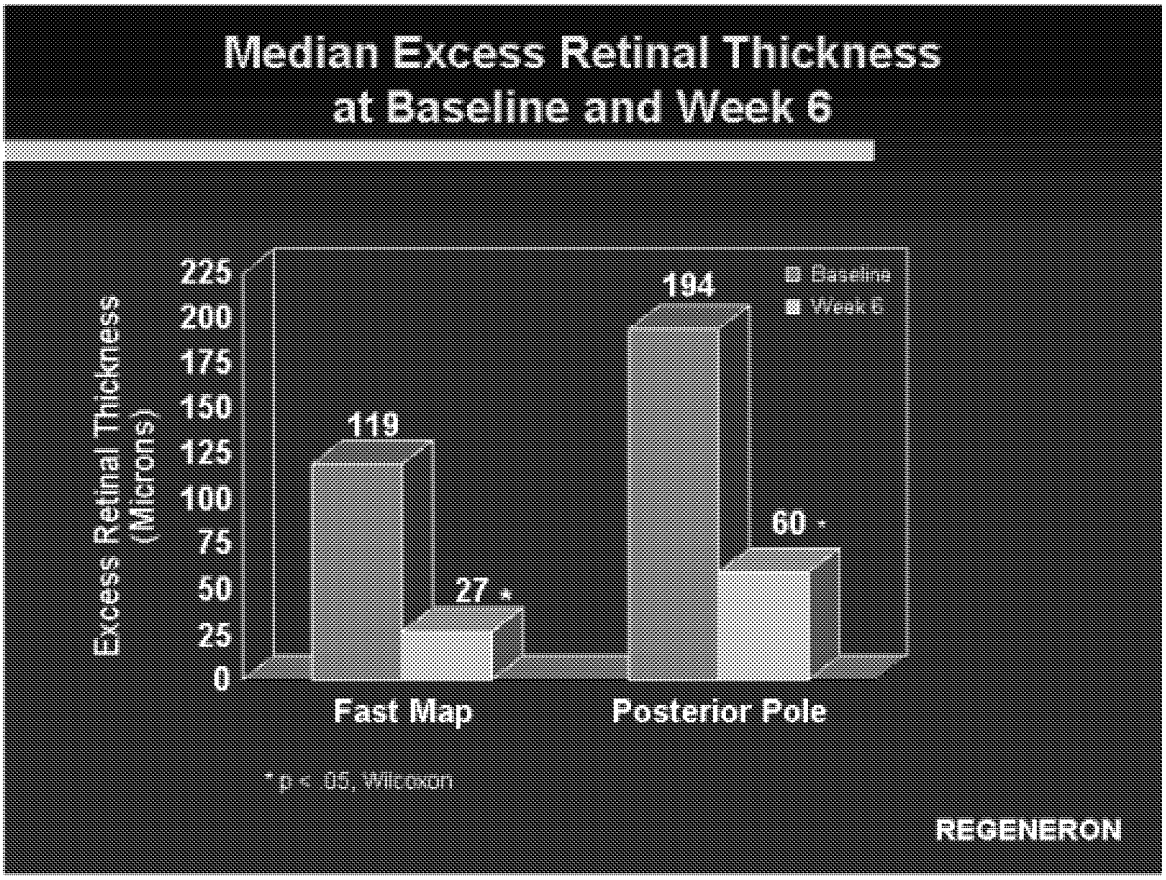
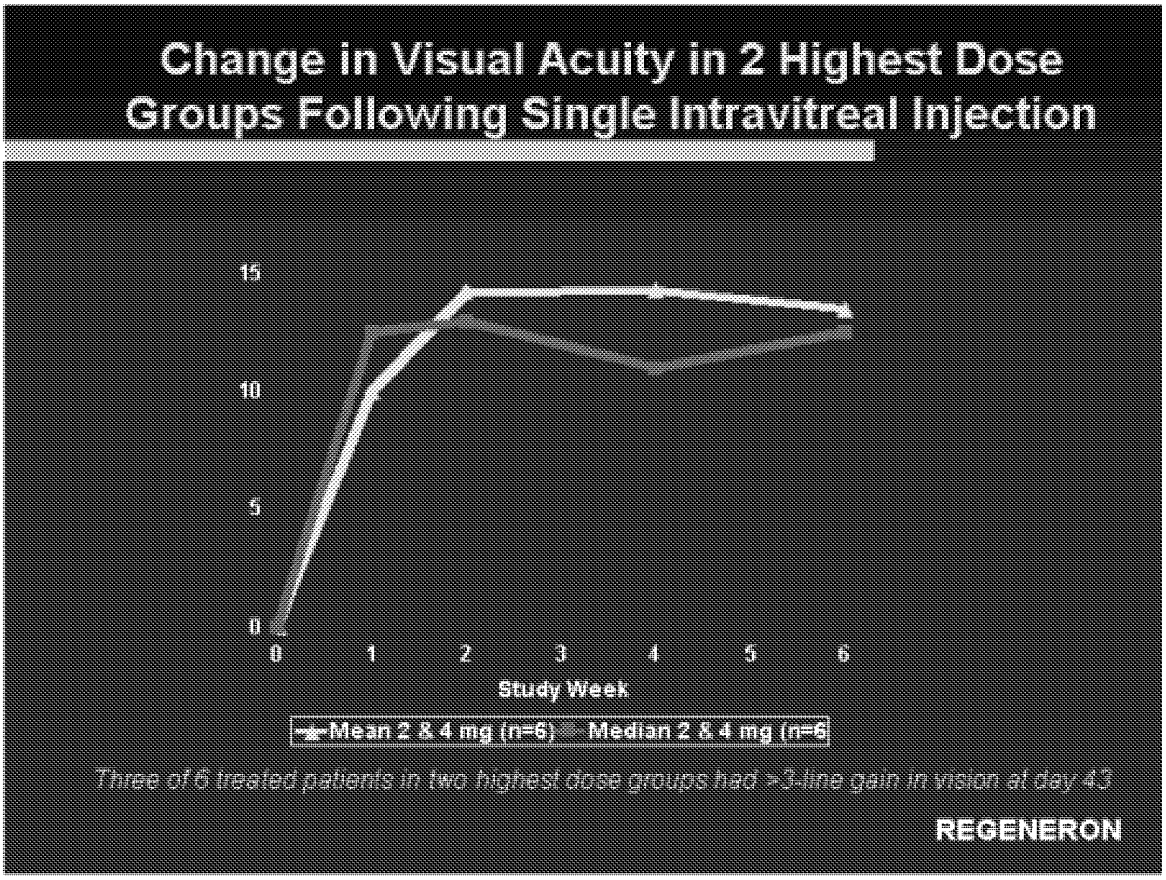

Intravitreal VEGF Trap – Eye
1.0 mg Single Dose
Baseline: 732µ
Week 1: 196µ
Week 2: 168µ
Week 8: 182µ
REGENERON


Median Excess Retinal Thickness
at Baseline and Week 6
Excess Retinal Thickness
(Microns)
225
200
175
150
125
100
75
50
25
0
119
27 *
194
60 *
Baseline
Week 6
Fast Map
Posterior Pole
* p < .05, Wilcoxon
REGENERON


Change in Visual Acuity in 2 Highest Dose Groups Following Single Intravitreal Injection
15
10
5
0
0
1
2
3
4
5
6
Study Week
Mean 2 & 4 mg (n=6)
Median 2 & 4 mg (n=6
Three of 6 treated patients in two highest dose groups had >3-line gain in vision at day 43
REGENERON

VEGF Trap – Eye Summary

- Confirmed evidence of biological activity
  - Rapid, substantial, and prolonged reduction in retinal thickness
  - Preliminary evidence for improved visual outcome
- Positioned for rapid expansion of program
  - Phase 2 wet AMD trial underway
  - DME pilot study underway
  - Potential partnering opportunity
- Phase 3 program in US likely to be comparison to ranibizumab (Lucentis™)
  - Initiation of phase 3 planned for 1Q 07

REGENERON

The IL-1 Trap Development Program

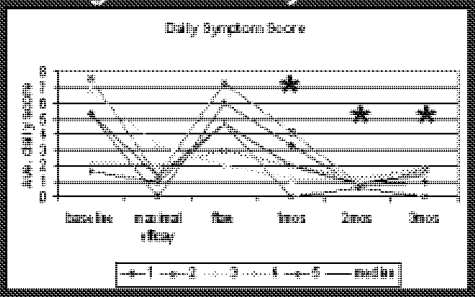
Registration study initiated in rare genetic diseases
4Q 2005

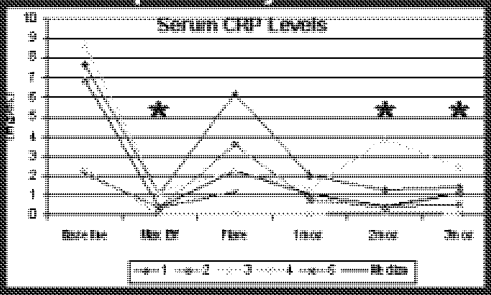
Proof-of-concept trial initiated in
Systemic Onset Juvenile Idiopathic Arthritis (SJIA)
4Q 2005

REGENERON

IL-1 Trap CAPS POC Study (5 patients)

- **IL-1 Trap rapidly and dramatically:**
  - Improves subjective measures of disease
  - Lowers blood markers of inflammation (e.g., CRP, SAA, ESR)
  - "Traps" IL-1 and convincingly confirms markedly increased IL-1 levels in this disease
- **No significant safety concerns noted in small pilot study**



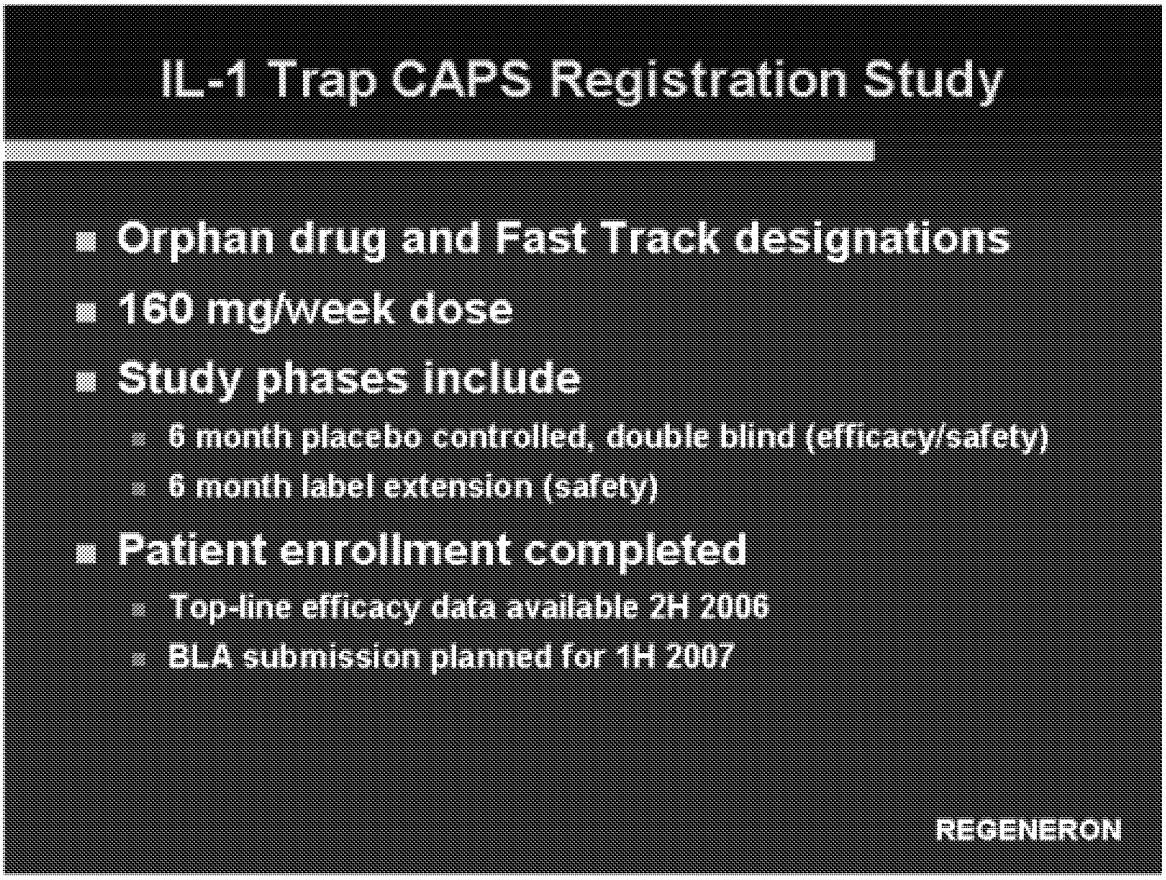


* : p<0.05 for comparison to baseline

* : p<0.05 for comparison to baseline

The daily diary score is the sum of symptoms on an ordinal (0-4) scale. Symptoms include fever, rash, joint pain, headache, hearing loss, fatigue, sleep problems, eye redness, & difficulties walking

REGENERON

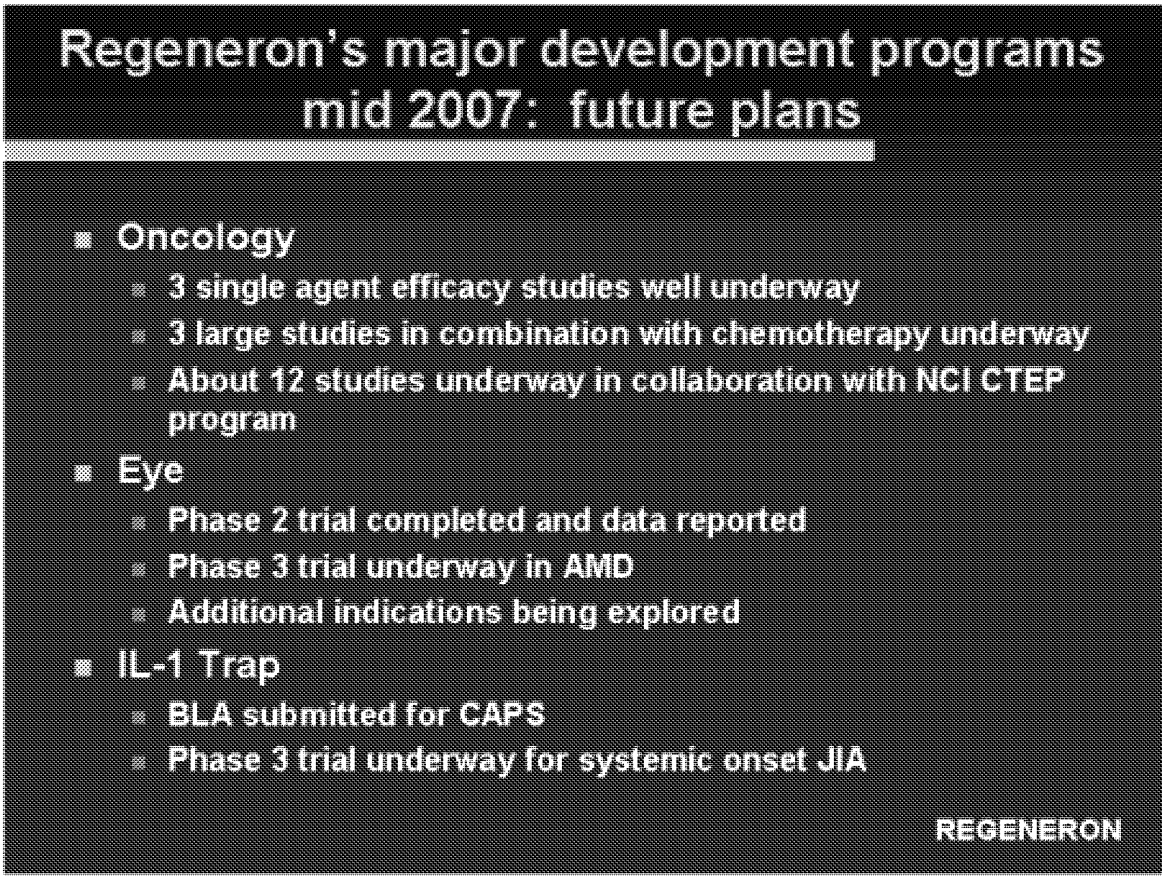

IL-1 Trap CAPS Registration Study
Orphan drug and Fast Track designations
160 mg/week dose
Study phases include
6 month placebo controlled, double blind (efficacy/safety)
6 month label extension (safety)
Patient enrollment completed
Top-line efficacy data available 2H 2006
BLA submission planned for 1H 2007
REGENERON

VelocImmune: Proprietary New Approach for Therapeutic Human Monoclonal Antibodies

- Produces wide variety of high affinity human antibodies against target
- Synergizes with commercial-scale manufacturing and proprietary approach to cell line development
- Applicable to both validated and novel targets
- Overcomes many issues currently used to produce human antibodies

Future Pipeline Development Platform

REGENERON


Regeneron's major development programs mid 2007: future plans
Oncology
3 single agent efficacy studies well underway
3 large studies in combination with chemotherapy underway
About 12 studies underway in collaboration with NCI CTEP program
Eye
Phase 2 trial completed and data reported
Phase 3 trial underway in AMD
Additional indications being explored
IL-1 Trap
BLA submitted for CAPS
Phase 3 trial underway for systemic onset JIA
REGENERON

Regeneron Pharmaceuticals, Inc.

Annual Shareholders Meeting

June 9, 2006

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
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Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 5/3/2007

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 3, 2007 (May 2, 2007)

REGENERON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

New York	000-19034	133444607
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 2.02 Results of Operations and Financial Condition.
Item 9.01 Financial Statements and Exhibits.
SIGNATURES
Exhibit Index
EX-99.1: PRESS RELEASE

Item 2.02 Results of Operations and Financial Condition.

On May 2, 2007, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 2007. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated May 2, 2007.

SIGNATURES

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 hereunto duly authorized.

Date: May 3, 2007

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski
Name: Stuart Kolinski
Title: Senior Vice President and General Counsel

Exhibit Index

Number	Description
99.1	Press Release dated May 2, 2007.

Exhibit 99.1

FOR IMMEDIATE RELEASE

REGENERON REPORTS FIRST QUARTER FINANCIAL AND OPERATING RESULTS

Tarrytown, New York (May 2, 2007) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the first quarter of 2007. The Company reported a net loss of $29.9 million, or $0.46 per share (basic and diluted) for the first quarter of 2007 compared with a net loss of $20.4 million, or $0.36 per share (basic and diluted) for the first quarter of 2006.

At March 31, 2007, cash, restricted cash, and marketable securities totaled $515.0 million compared with $522.9 million at December 31, 2006. In the first quarter of 2007, the Company entered into non-exclusive license agreements with AstraZeneca UK Limited and Astellas Pharma Inc. with respect to the Company's *VelocImmune*® technology for generating human monoclonal antibody product candidates, as described below. In connection with these agreements, AstraZeneca and Astellas each made an up-front payment to the Company of $20.0 million in February and April 2007, respectively.

The Company's $200.0 million of convertible notes, which bear interest at 5.5% per annum, mature in October 2008.

Current Business Highlights

Regeneron is currently focused on three clinical development programs: IL-1 Trap (rilonacept) in various inflammatory indications, the VEGF Trap in oncology, and the VEGF Trap-Eye in eye diseases. The Company also is developing its pipeline of preclinical antibody candidates discovered utilizing its *VelocImmune* technology.

The VEGF Trap-Eye, a specially purified and formulated form of the VEGF Trap for use in intraocular applications, is being developed in collaboration with Bayer HealthCare AG. The development program in eye disease is expected to total over $250 million over the next several years, with the Company and Bayer HealthCare sharing the costs. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. The development program in oncology is expected to total over $400 million over the next several years, which will be funded by sanofi-aventis.

IL-1 Trap — Inflammatory Diseases

Regeneron recently completed the 24-week open-label safety extension phase of the Phase 3 clinical program for the IL-1 Trap in patients suffering from a rare chronic disease known as CAPS (Cryopyrin-Associated Periodic Syndromes). Regeneron is currently preparing to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for CAPS this quarter. The FDA has granted Orphan Drug status and Fast Track designation to the IL-1 Trap for the treatment of CAPS.

The Phase 3 program included two efficacy studies in which the IL-1 Trap markedly reduced disease activity in subjects with this rare chronic disease. The primary endpoint, which was met in both studies, was the change in disease activity, as measured by a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

Regeneron also is evaluating the potential use of the IL-1 Trap in other indications in which IL-1 may play a role. Based on preclinical evidence that IL-1 appears to play a critical role in gout, the Company initiated a proof of concept study of the IL-1 Trap in gout in the first quarter of 2007. The Company also is preparing to initiate exploratory proof of concept studies of the IL-1 Trap in other indications.

VEGF Trap — Eye Diseases

In the clinical development program for the VEGF Trap-Eye, Bayer HealthCare and Regeneron currently are conducting a Phase 2 trial of the VEGF Trap-Eye in the neovascular form of age-related macular degeneration (wet AMD). This trial is evaluating the safety and biological effect of intravitreal administration of the VEGF Trap-Eye using different doses and different dosing regimens. In March 2007, the companies announced positive preliminary data from a pre-planned interim analysis of this study. The VEGF Trap-Eye met its primary endpoint of a statistically significant reduction in retinal thickness after 12 weeks compared with baseline (all groups combined, decrease of 135 microns, $p < 0.0001$). Mean change from baseline in visual acuity, a key secondary endpoint of the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.9 letters, $p < 0.0001$). Moreover, patients in the dose groups that received only a single dose, on average, demonstrated a decrease in excess retinal thickness ($p < 0.0001$) and an increase in visual acuity ($p = 0.012$) at 12 weeks. There were no drug-related serious adverse events, and treatment with the VEGF Trap-Eye was generally well-tolerated. The most common adverse events were those typically associated with intravitreal injections. Detailed data from this interim analysis are scheduled for presentation at an upcoming scientific conference.

Based on these results, Regeneron and Bayer HealthCare plan to initiate the VEGF Trap-Eye Phase 3 program later this year. The companies are collaborating on the global development of the VEGF Trap-Eye for the treatment of wet AMD, diabetic eye diseases, and other eye diseases and disorders. Bayer HealthCare and Regeneron will jointly commercialize the VEGF Trap-Eye outside the United States, and Regeneron maintains exclusive rights in the United States.

VEGF Trap — Oncology

Regeneron and sanofi-aventis are conducting a broad-based clinical development program for the VEGF Trap in different cancer indications. Currently, the companies are conducting Phase 2 single-agent studies, with patient enrollment underway in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients

with symptomatic malignant ascites (SMA). Earlier this year, sanofi-aventis reported that a registration filing is possible for the VEGF Trap in at least one of these single-agent indications in 2008. Sanofi-aventis and Regeneron also announced that they intend to conduct five Phase 3 trials evaluating the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer types, with at least three of these trials planned to begin in 2007. Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the planned Phase 3 clinical program.

In addition, six new Phase 2 single-agent studies have begun in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) in several different cancer types. These trials will evaluate the VEGF Trap in single-agent trials as well as in combination with chemotherapy regimens. The companies are working to finalize plans with NCI/CTEP for at least four additional trials in different cancer types.

Monoclonal Antibodies

VelocImmune, Regeneron's novel technology for producing fully human monoclonal antibodies, is part of the Company's suite of proprietary, inter-related technology platforms that are designed to provide Regeneron with its next generation of therapeutic candidates. Regeneron plans to move its first new antibody product candidate into clinical trials in the fourth quarter of 2007, with plans to advance at least two antibody product candidates into human clinical trials each year going forward.

In 2007, Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that will allow those companies to utilize *VelocImmune* technology in their internal research programs to discover human monoclonal antibody product candidates. Each of those companies made a $20.0 million up-front, non-refundable payment and will make up to five additional annual payments of $20.0 million, subject to the ability to terminate the agreement after making the first three additional payments. Upon commercialization of any antibody products discovered utilizing

VelocImmune, the licensees will pay to Regeneron a mid-single-digit royalty on product sales.

Financial Results

Regeneron's total revenue decreased to $15.8 million in the first quarter of 2007 from $18.2 million in the same period of 2006. Contract research and development revenue in the first quarters of 2007 and 2006 principally related to the Company's VEGF Trap collaboration with sanofi-aventis in cancer indications. Contract manufacturing revenue in 2006 related to Regeneron's long-term manufacturing agreement with Merck & Co., Inc., which expired in October 2006. Technology licensing revenue in the first quarter of 2007 related to the Company's license agreement with AstraZeneca, as described below.

Regeneron recognized contract research and development revenue of $11.8 million in the first quarter of 2007 related to the Company's collaboration with sanofi-aventis, compared with $13.9 million in the same period of 2006. Contract research and development revenue from the sanofi-aventis collaboration consisted of reimbursement of VEGF Trap development expenses plus recognition of amounts related to $105.0 million of previously received and deferred up-front, non-refundable payments. Reimbursement of expenses decreased to $9.6 million in the first quarter of 2007 from $10.8 million in the same period of 2006, principally because costs related to the Company's manufacture of VEGF Trap clinical supplies were lower in 2007. With respect to the up-front payments from sanofi-aventis, $2.2 million was recognized as revenue in the first quarter of 2007 compared to $3.1 million in the same quarter of 2006.

Sanofi-aventis also incurs VEGF Trap development expenses directly and these expenses are increasing because of the growing number of clinical trials sanofi-aventis is overseeing in the VEGF Trap oncology program. During the term of the collaboration, sanofi-aventis pays 100% of agreed-upon VEGF Trap development expenses incurred by both companies. Following commercialization of a VEGF Trap product by the collaboration, Regeneron, from its 50% share of VEGF Trap profits, will reimburse sanofi-

aventis for 50% of the VEGF Trap development expenses previously paid by sanofi-aventis.

In October 2006, the Company entered into a collaboration with Bayer HealthCare for the development and commercialization of the VEGF Trap-Eye outside the United States, and received a $75.0 million up-front, non-refundable payment which was recorded as deferred revenue. In 2007, 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 $50.0 million will be shared equally; Regeneron is solely responsible for the next $40.0 million; over $90.0 million will be shared equally. Bayer HealthCare reimbursements of shared development expenses incurred by the Company are recorded as deferred revenue. When the Company and Bayer HealthCare have formalized their global development plans for the VEGF Trap-Eye and the projected responsibilities of each of the companies under those plans, the Company will begin recognizing contract research and development revenue related to payments from Bayer HealthCare, including the $75.0 million up-front payment. The Company recognizes revenue from collaborations in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* and FASB Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables.*

Under the terms of the Company's license agreement with AstraZeneca, the Company received a $20.0 million non-refundable, up-front payment in February 2007 which was deferred and will be recognized as revenue ratably over approximately the first year of the agreement. In the first quarter of 2007, the Company recognized $2.1 million of technology licensing revenue related to the AstraZeneca agreement.

Total operating expenses for the first quarter of 2007 were $49.4 million, 24 percent higher than the same period in 2006. Operating expenses in the first quarter of 2007 and 2006 include a total of $6.6 million and $3.9 million, respectively, of non-cash

compensation expense related to employee stock option awards (Stock Option Expense), as follows:

For the three months ended March 31,

(in millions)	2007		
Expenses	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 37.4	$ 3.8	$ 41.2
General and administrative	5.4	2.8	8.2
Total operating expenses	$ 42.8	$ 6.6	$ 49.4

For the three months ended March 31,

(in millions)	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

The increase in total Stock Option Expense in the first quarter of 2007 was primarily due to the higher fair market value of the Company's Common Stock on the date of annual employee option grants made by the Company in December 2006 in comparison to the fair market value of the Company's Common Stock on the dates of annual employee option grants made in recent prior years.

Research and development (R&D) expenses increased to $41.2 million in the first quarter of 2007 from $32.1 million in the comparable quarter of 2006. In addition to the impact of Stock Option Expense, as described above, in the first quarter of 2007, the Company incurred higher costs related to advancing new antibody candidates into preclinical development and higher development expenses for the VEGF Trap-Eye and IL-1 Trap, which were partly offset by lower development expenses for the VEGF Trap cancer program.

About Regeneron Pharmaceuticals

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, and has preclinical programs in other diseases and disorders.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2006. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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Media:
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ltortorete@biosector2.com

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	March 31, 2007	December 31, 2006
ASSETS		
Cash, restricted cash, and marketable securities	$ 514,975	$ 522,859
Receivables	33,632	7,493
Property, plant, and equipment, net	47,781	49,353
Other assets	5,043	5,385
Total assets	$ 601,431	$ 585,090
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 20,081	$ 21,471
Deferred revenue	184,661	146,995
Notes payable	200,000	200,000
Stockholders' equity	196,689	216,624
Total liabilities and stockholders' equity	$ 601,431	$ 585,090

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended March 31,	
	2007	**2006**
Revenues		
Contract research and development	$ 13,645	$ 14,587
Contract manufacturing		3,632
Technology licensing	2,143	
	15,788	18,219
Expenses		
Research and development	41,235	32,084
Contract manufacturing		1,852
General and administrative	8,202	5,946
	49,437	39,882
Loss from operations	(33,649)	(21,663)
Other income (expense)		
Investment income	6,743	3,481
Interest expense	(3,011)	(3,011)
	3,732	470
Net loss before cumulative effect of a change in accounting principle	(29,917)	(21,193)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")		813
Net loss	($29,917)	($20,380)
Net loss per share amounts, basic and diluted:		
Net loss before cumulative effect of a change in accounting principle	($0.46)	($0.37)
Cumulative effect of adopting SFAS 123R		0.01
Net loss	($0.46)	($0.36)
Weighted average shares outstanding, basic and diluted	65,563	56,727

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 6/8/2007

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934

Date of Report (Date of earliest event reported): June 8, 2007

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**000-19034**	**133444607**
(State or other jurisdiction of incorporation)	(Commission File Number)	**(I.R.S. Employer Identification Number)**

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 4905

Samsung Bioepis Exhibit 1017, pg. 4905

Item 8.01 Other Events

On June 8, 2007, Regeneron's President and Chief Executive Officer, Dr. Leonard Schleifer, is scheduled to present a brief report on Regeneron's business at the company's Annual Meeting of Shareholders to be held at the Westchester Marriott Hotel, 670 White Plains Road, Tarrytown, New York. The overheads for this presentation are furnished as Exhibit 99(a) to this Form 8-K.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Overheads for presentation at Regeneron's Annual Meeting of Shareholders to be held on June 8, 2007.

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Dated: June 8, 2007

By: /s/ Stuart Kolinski
Stuart Kolinski
Vice President and General Counsel

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 4906

Samsung Bioepis Exhibit 1017, pg. 4906

Exhibit Index

Number	Description
99(a)	Overheads for presentation at Regeneron's Annual Meeting of Shareholders to be held on June 8, 2007.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
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Samsung Bioepis Exhibit 1017, pg. 4907

REGENERON

Annual Meeting of Shareholders
June 8, 2007

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 4909

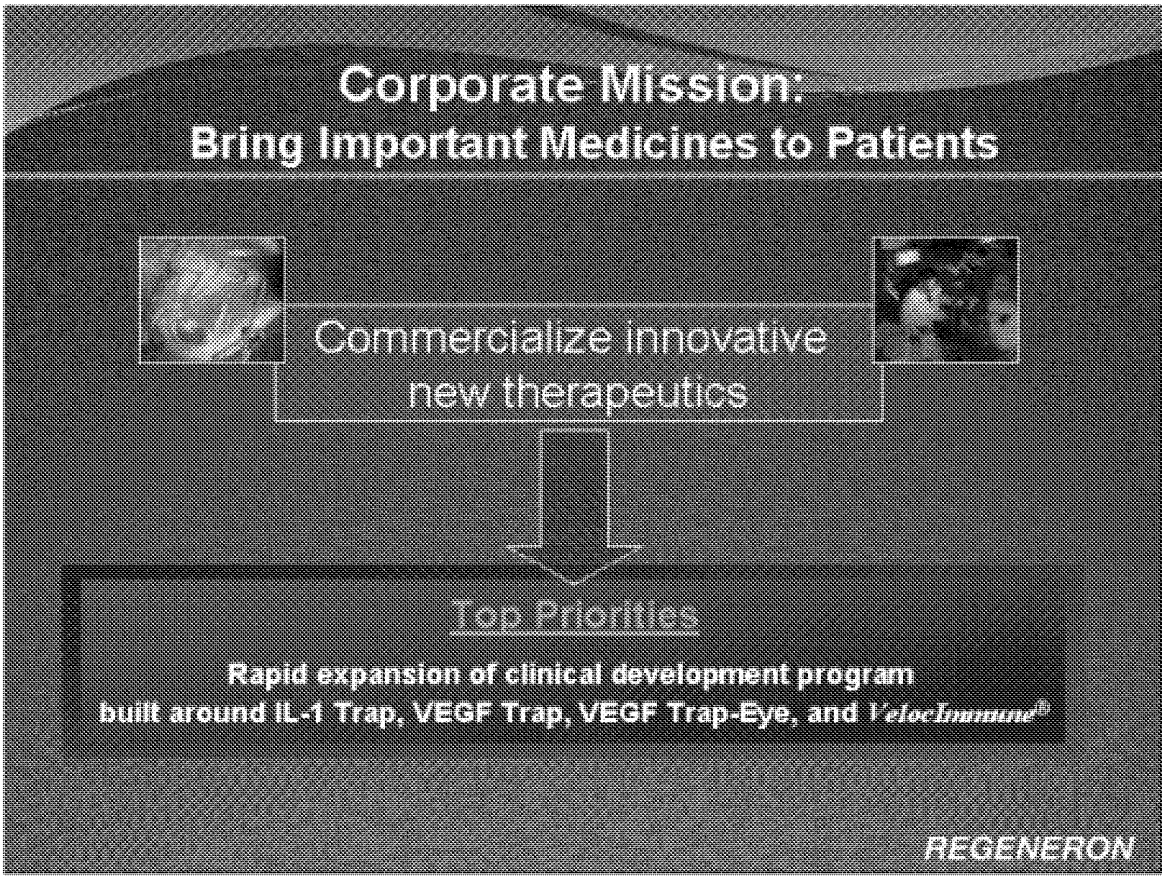
Samsung Bioepis Exhibit 1017, pg. 4909

Safe Harbor Statement

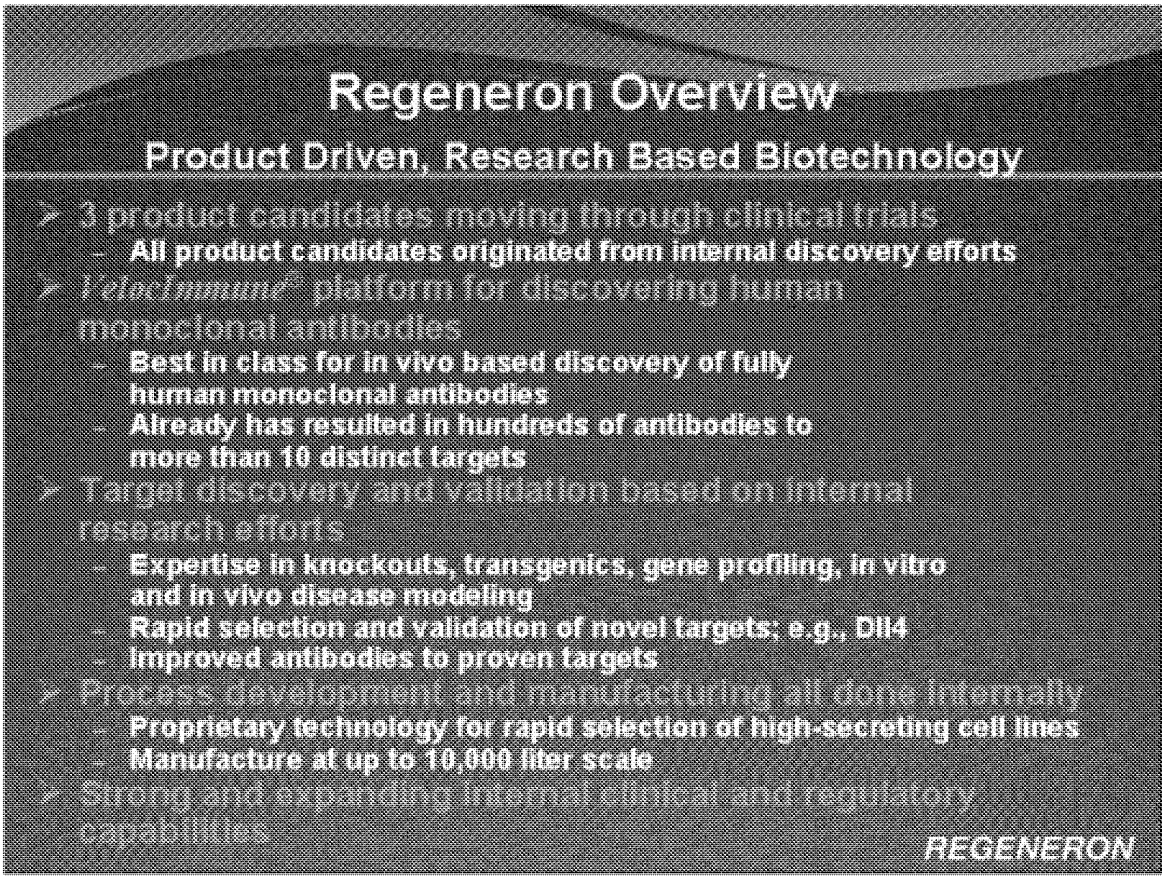
Except for historical information, the matters contained in this presentation may constitute forward-looking statements that involve risks and uncertainties, including uncertainties related to product development and clinical trials, unforeseen safety issues resulting from the administration of products in patients, uncertainties related to the need for regulatory and other government approvals, patents and proprietary technology, the need for additional capital, uncertainty of market acceptance of Regeneron's product candidates, the receipt of future payments, the continuation of business partnerships, and additional risks detailed from time to time in Regeneron's filings with the Securities and Exchange Commission (SEC). Please refer to Regeneron's recent Forms 10-K, 10-Q, and 8-K for additional information on the uncertainties and risk factors related to our business.

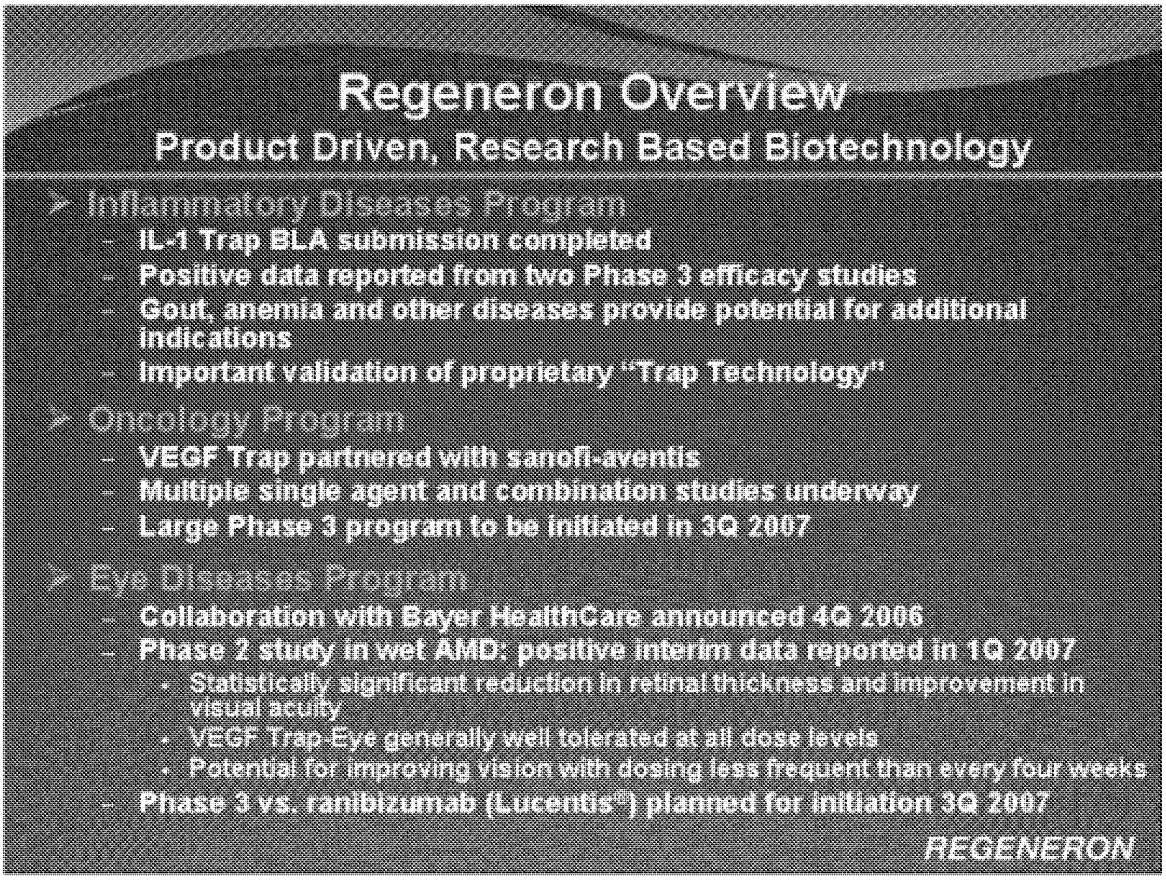
Because forward-looking statements involve risks and uncertainties, actual results may differ materially from current results expected by Regeneron. Regeneron is providing this information as of the original date of this presentation and expressly disclaims any duty to update any information contained in these materials.

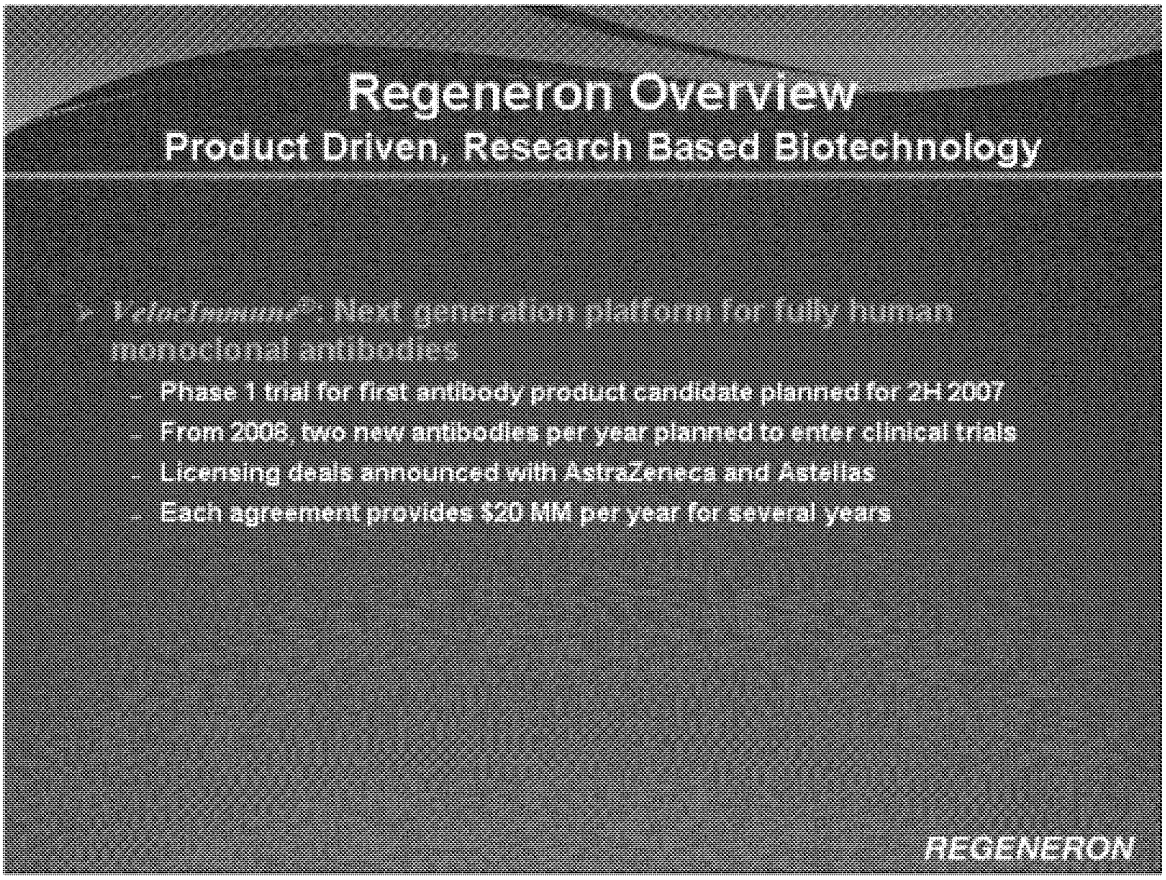
REGENERON


Corporate Mission:
Bring Important Medicines to Patients
Commercialize innovative new therapeutics
Top Priorities
Rapid expansion of clinical development program
built around IL-1 Trap, VEGF Trap, VEGF Trap-Eye, and VelocImmune®
REGENERON

Business Strategy
Develop fully integrated business capabilities
Discovery, preclinical and clinical development, regulatory, manufacturing, marketing
Collaborate with firms that expand development and commercial possibilities of product candidates
Retain substantial economic interest in product candidates
Expand clinical development pipeline through innovative antibody platform
Revenue generation through *VelocImmune*® licensing
REGENERON


Regeneron Overview
Product Driven, Research Based Biotechnology
3 product candidates moving through clinical trials
All product candidates originated from internal discovery efforts
VelocImmune® platform for discovering human monoclonal antibodies
Best in class for in vivo based discovery of fully human monoclonal antibodies
Already has resulted in hundreds of antibodies to more than 10 distinct targets
Target discovery and validation based on internal research efforts
Expertise in knockouts, transgenics, gene profiling, in vitro and in vivo disease modeling
Rapid selection and validation of novel targets: e.g., Dll4
Improved antibodies to proven targets
Process development and manufacturing all done internally
Proprietary technology for rapid selection of high-secreting cell lines
Manufacture at up to 10,000 liter scale
Strong and expanding internal clinical and regulatory capabilities
REGENERON


Regeneron Overview
Product Driven, Research Based Biotechnology
Inflammatory Diseases Program
IL-1 Trap BLA submission completed
Positive data reported from two Phase 3 efficacy studies
Gout, anemia and other diseases provide potential for additional indications
Important validation of proprietary "Trap Technology"
Oncology Program
VEGF Trap partnered with sanofi-aventis
Multiple single agent and combination studies underway
Large Phase 3 program to be initiated in 3Q 2007
Eye Diseases Program
Collaboration with Bayer HealthCare announced 4Q 2006
Phase 2 study in wet AMD: positive interim data reported in 1Q 2007
Statistically significant reduction in retinal thickness and improvement in visual acuity
VEGF Trap-Eye generally well tolerated at all dose levels
Potential for improving vision with dosing less frequent than every four weeks
Phase 3 vs. ranibizumab (Lucentis®) planned for initiation 3Q 2007
REGENERON


Regeneron Overview
Product Driven, Research Based Biotechnology
VelocImmune®: Next generation platform for fully human monoclonal antibodies
Phase 1 trial for first antibody product candidate planned for 2H 2007
From 2008, two new antibodies per year planned to enter clinical trials
Licensing deals announced with AstraZeneca and Astellas
Each agreement provides $20 MM per year for several years
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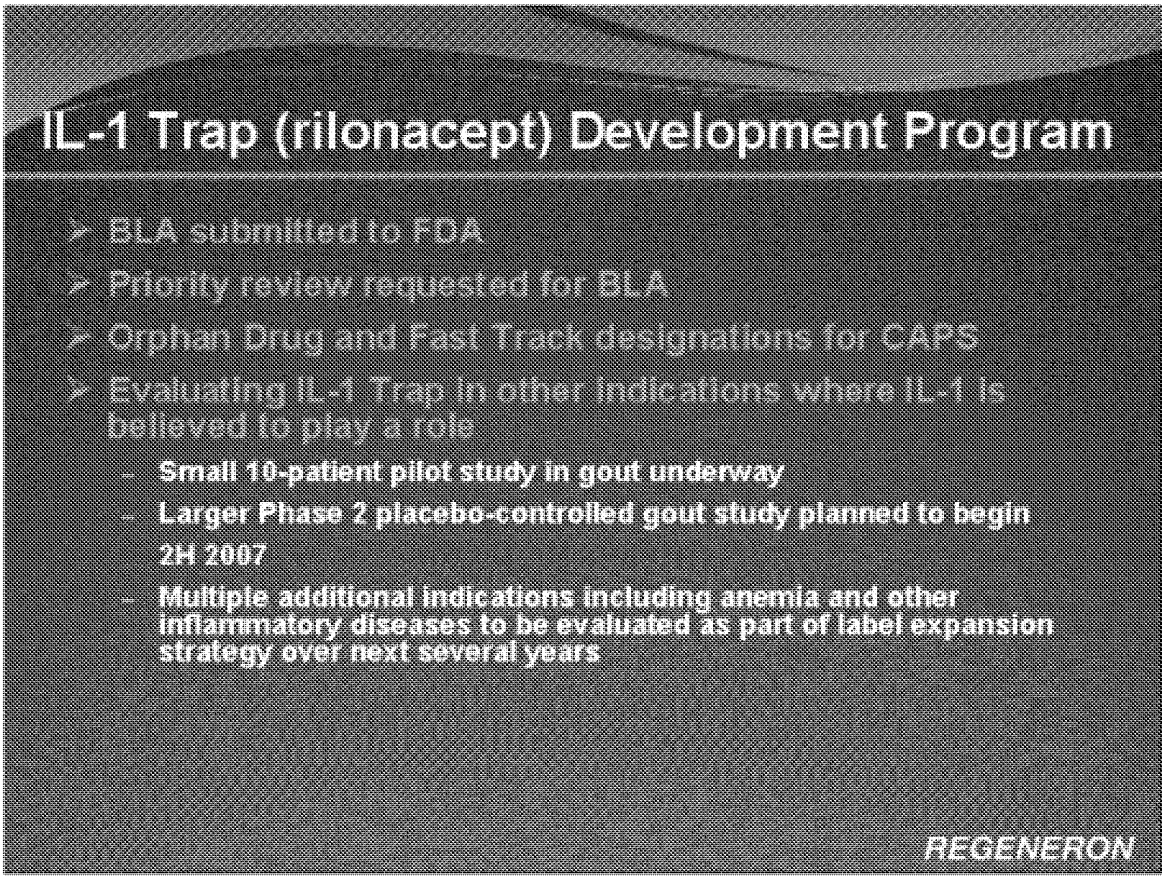
IL-1 Trap (rilonacept) Development Program
BLA submitted to FDA
Priority review requested for BLA
Orphan Drug and Fast Track designations for CAPS
Evaluating IL-1 Trap in other indications where IL-1 is believed to play a role
Small 10-patient pilot study in gout underway
Larger Phase 2 placebo-controlled gout study planned to begin 2H 2007
Multiple additional indications including anemia and other inflammatory diseases to be evaluated as part of label expansion strategy over next several years
REGENERON

Diseases of the "Inflammasome"

- Inflammasome
  - **Multi-protein intracellular system including cryopyrin ("*CIAS1*" gene product or Nalp3)**
  - **Activated by "danger signals"**
  - **Leads to processing and release of Interleukin-1**
- Mutations in *CIAS1* lead to auto-inflammatory syndromes
- Inflammatory response to uric acid crystals (gout) mediated by inflammasome
  - **Interleukin-1 key mediator of gout inflammation**
- Excessive activation of inflammasome may be key part of many inflammatory diseases

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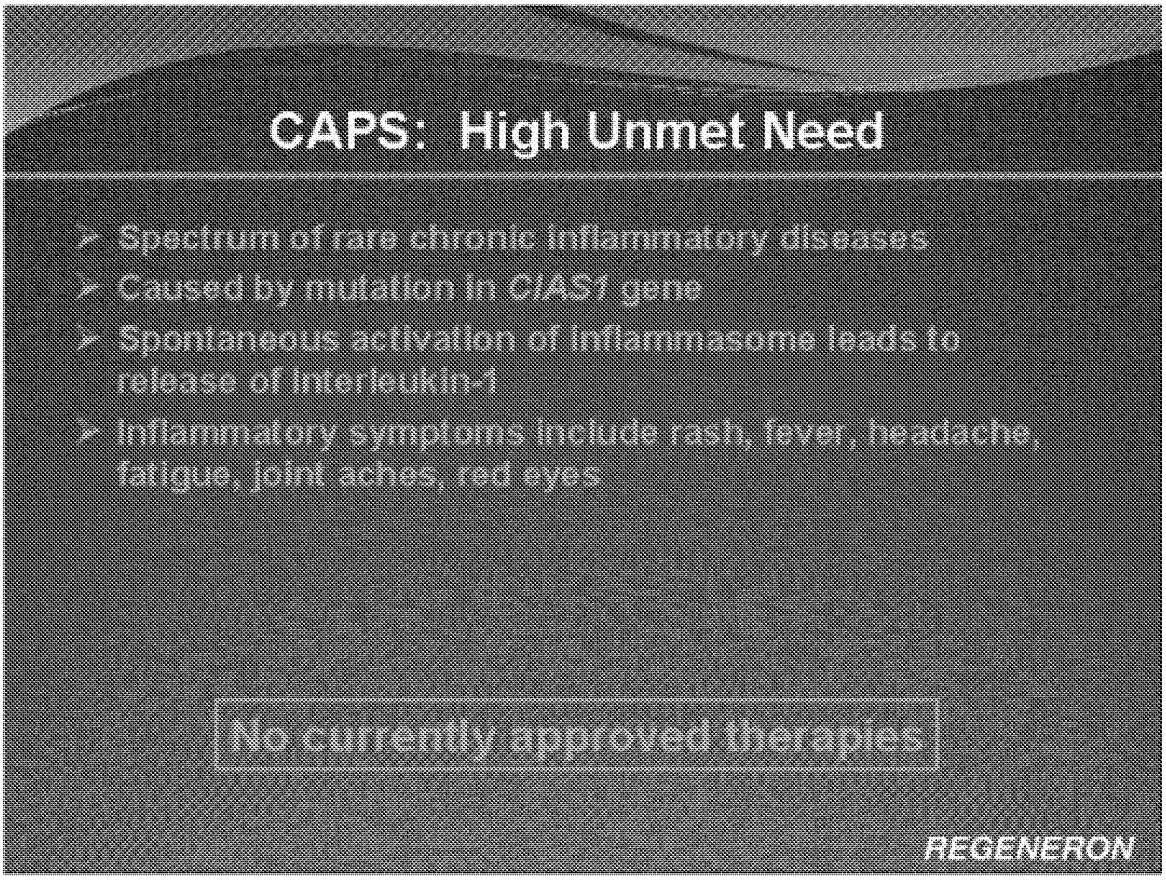
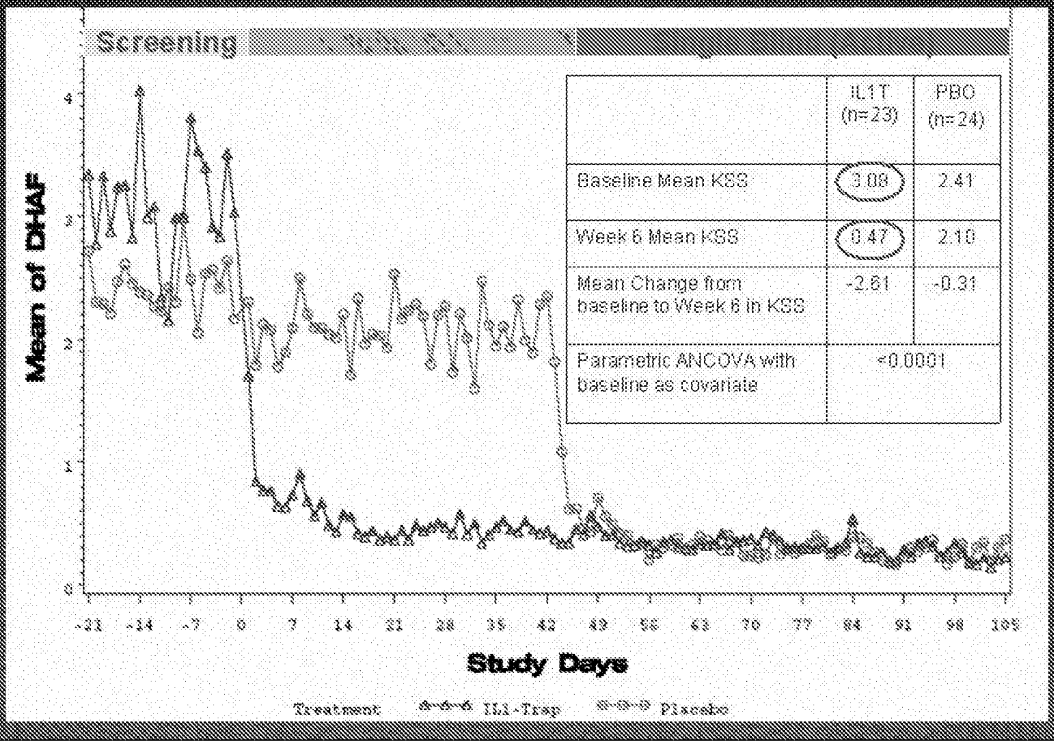

CAPS: High Unmet Need
Spectrum of rare chronic inflammatory diseases
Caused by mutation in CIAS1 gene
Spontaneous activation of inflammasome leads to release of Interleukin-1
Inflammatory symptoms include rash, fever, headache, fatigue, joint aches, red eyes
No currently approved therapies
REGENERON

CAPS Phase 3 Pivotal Trial – Part A

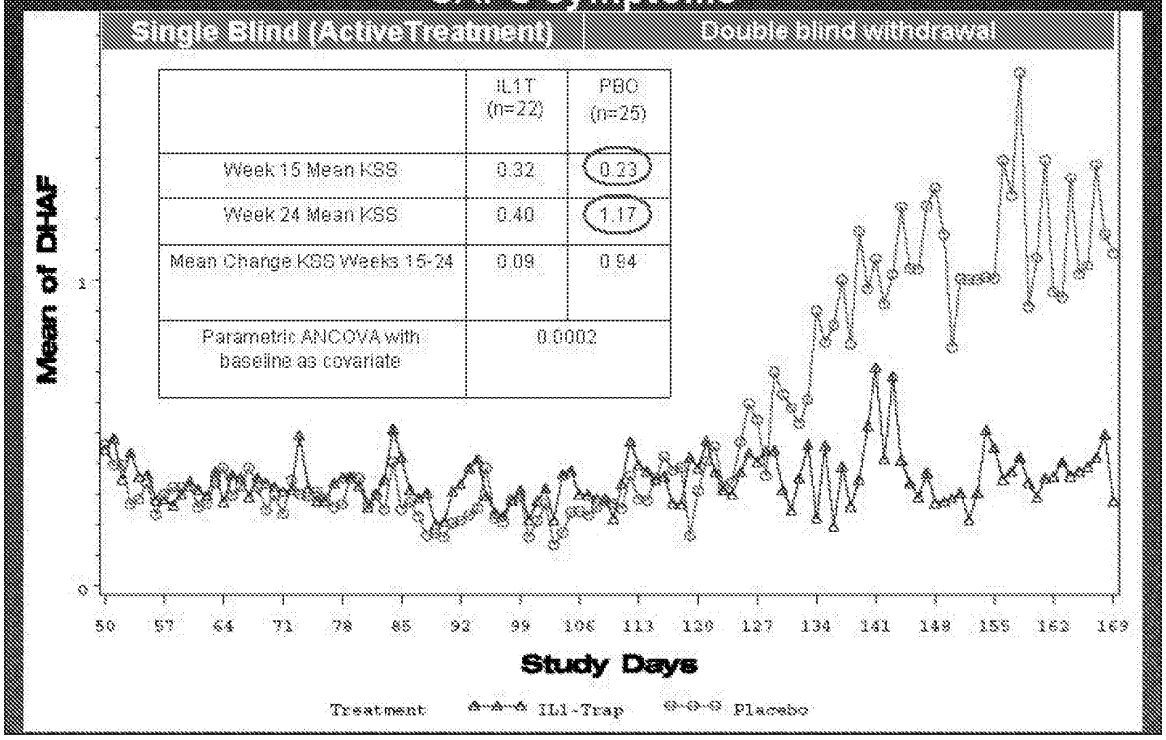
IL-1 Trap provides rapid control of signs and symptoms



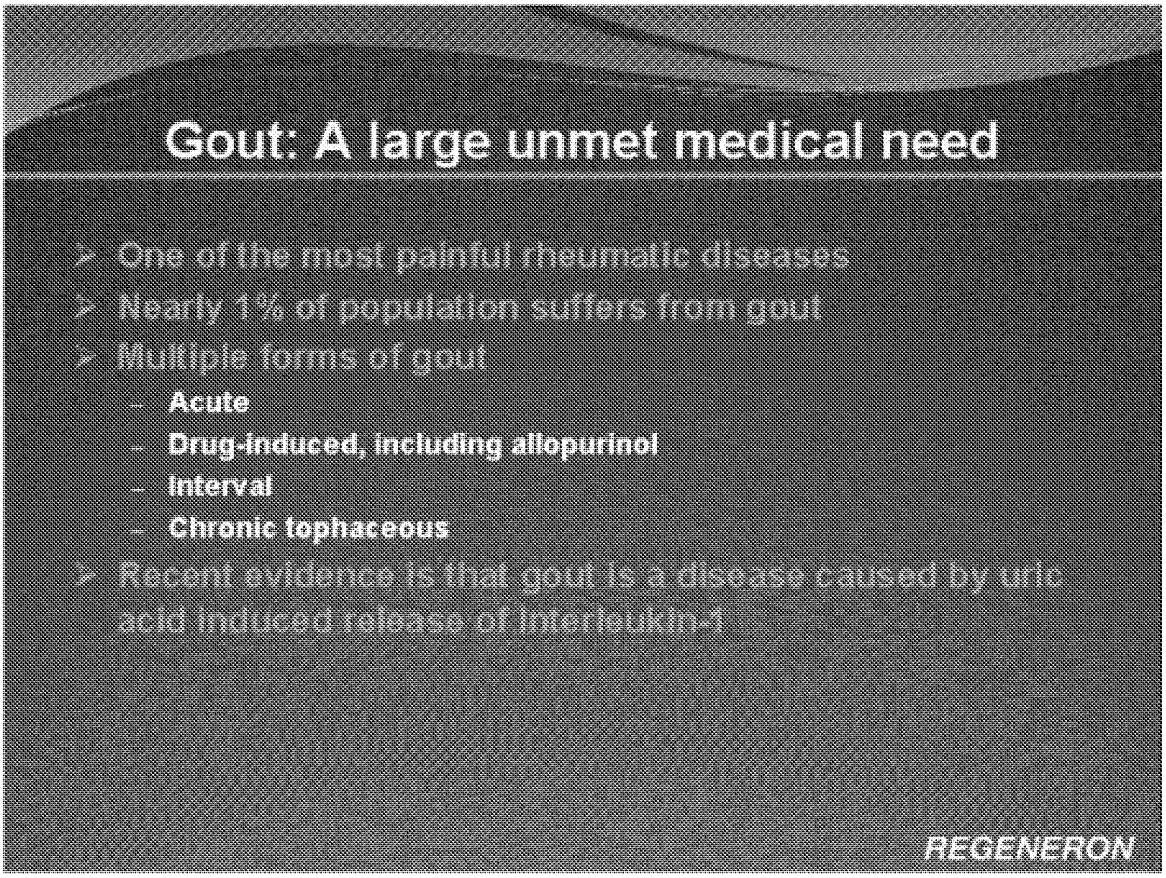
	IL1T (n=23)	PBO (n=24)
Baseline Mean KSS	3.08	2.41
Week 6 Mean KSS	0.47	2.10
Mean Change from baseline to Week 6 in KSS	-2.61	-0.31
Parametric ANCOVA with baseline as covariate	<0.0001	

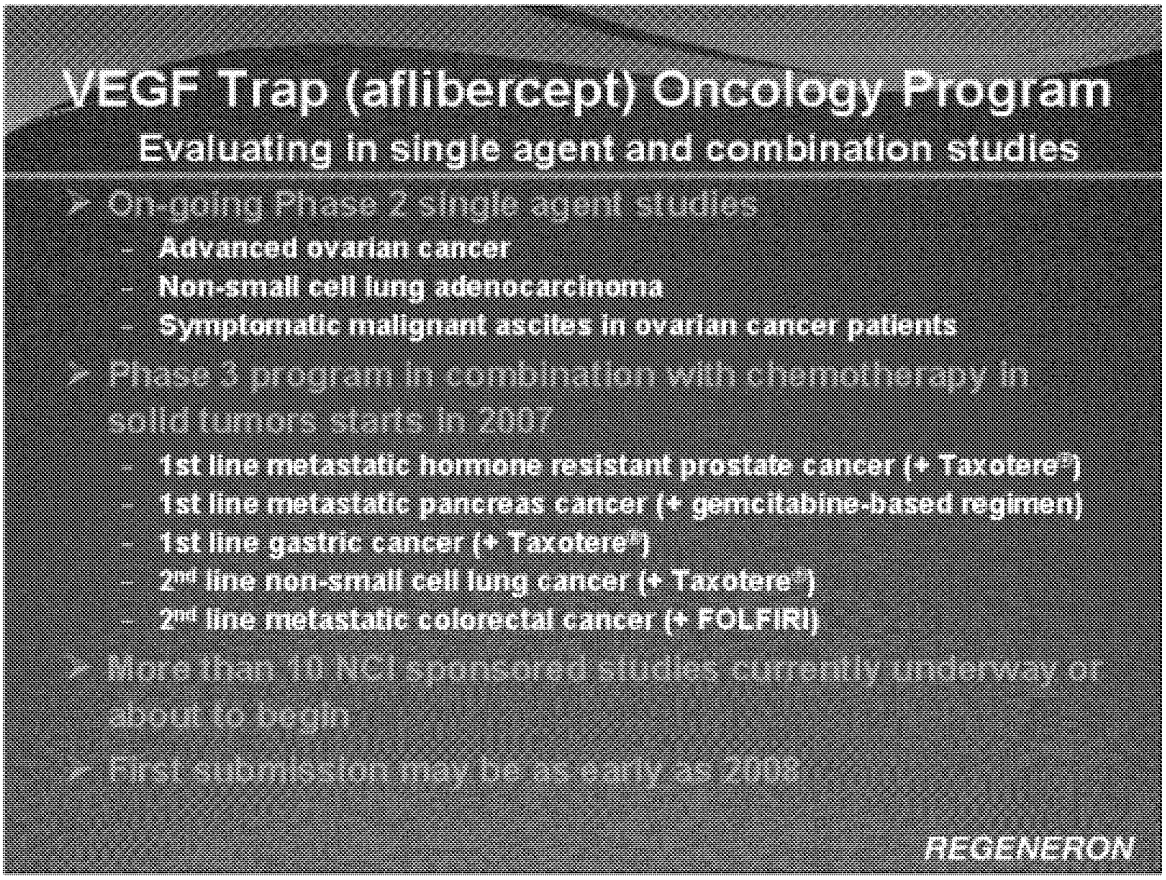
CAPS Phase 3 Pivotal Trial – Part B

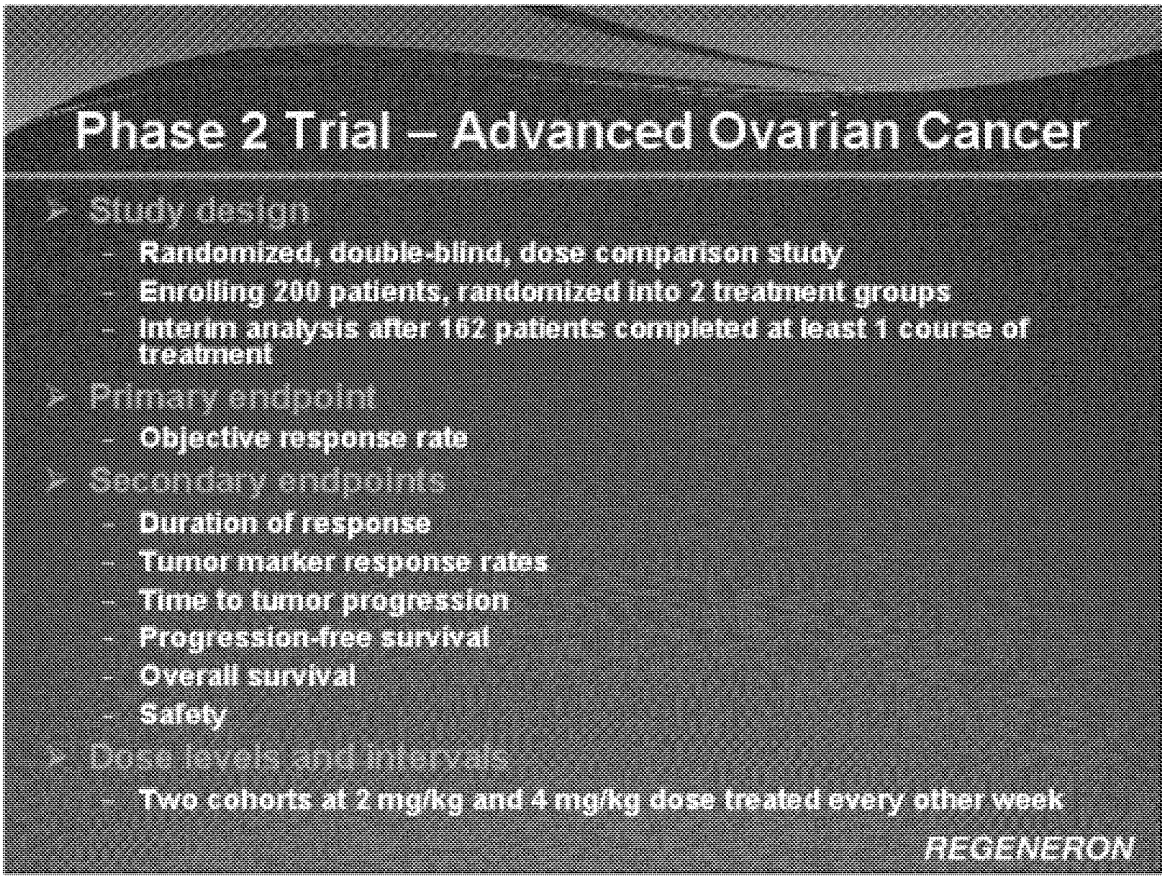
Randomized withdrawal confirms continued reduction of CAPS symptoms

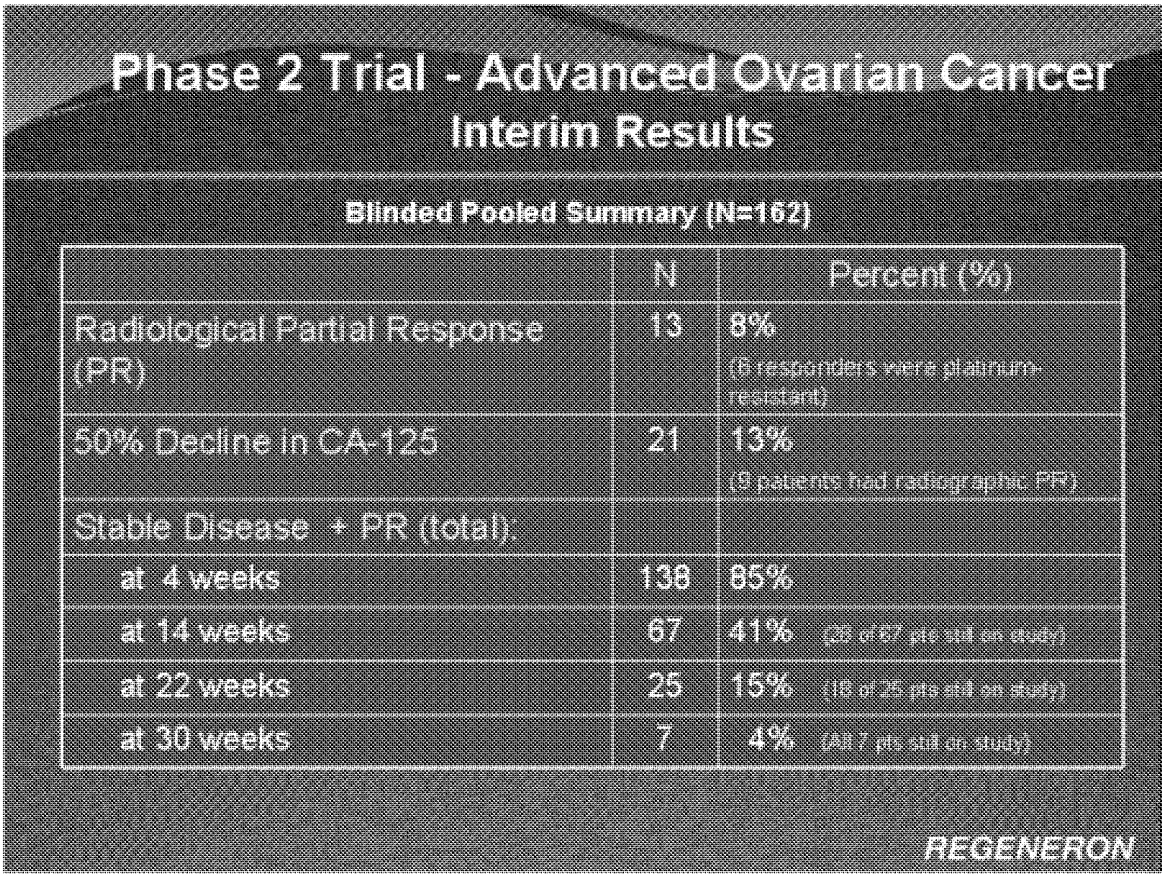


	IL1T (n=22)	PBO (n=25)
Week 15 Mean KSS	0.32	0.23
Week 24 Mean KSS	0.40	1.17
Mean Change KSS Weeks 15-24	0.09	0.94
Parametric ANCOVA with baseline as covariate	0.0002	


Gout: A large unmet medical need
One of the most painful rheumatic diseases
Nearly 1% of population suffers from gout
Multiple forms of gout
Acute
Drug-induced, including allopurinol
Interval
Chronic tophaceous
Recent evidence is that gout is a disease caused by uric acid induced release of interleukin-1
REGENERON


VEGF Trap (aflibercept) Oncology Program
Evaluating in single agent and combination studies
On-going Phase 2 single agent studies
Advanced ovarian cancer
Non-small cell lung adenocarcinoma
Symptomatic malignant ascites in ovarian cancer patients
Phase 3 program in combination with chemotherapy in solid tumors starts in 2007
1st line metastatic hormone resistant prostate cancer (+ Taxotere®)
1st line metastatic pancreas cancer (+ gemcitabine-based regimen)
1st line gastric cancer (+ Taxotere®)
2nd line non-small cell lung cancer (+ Taxotere®)
2nd line metastatic colorectal cancer (+ FOLFIRI)
More than 10 NCI sponsored studies currently underway or about to begin
First submission may be as early as 2008
REGENERON


Phase 2 Trial – Advanced Ovarian Cancer
Study design
Randomized, double-blind, dose comparison study
Enrolling 200 patients, randomized into 2 treatment groups
Interim analysis after 162 patients completed at least 1 course of treatment
Primary endpoint
Objective response rate
Secondary endpoints
Duration of response
Tumor marker response rates
Time to tumor progression
Progression-free survival
Overall survival
Safety
Dose levels and intervals
Two cohorts at 2 mg/kg and 4 mg/kg dose treated every other week
REGENERON


Phase 2 Trial - Advanced Ovarian Cancer
Interim Results
Blinded Pooled Summary (N=162)
N
Percent (%)
Radiological Partial Response (PR)
13
8%
(6 responders were platinum-resistant)
50% Decline in CA-125
21
13%
(9 patients had radiographic PR)
Stable Disease + PR (total):
at 4 weeks
138
85%
at 14 weeks
67
41%
(28 of 67 pts still on study)
at 22 weeks
25
15%
(16 of 25 pts still on study)
at 30 weeks
7
4%
(All 7 pts still on study)
REGENERON

Phase 2 Trial - Advanced Ovarian Cancer Interim Results

	N	Percent (%)
Investigator assessment of Ascites response		
23 patients with evaluable baseline ascites		
Complete disappearance of ascites	7	29%
No increase in ascites	13	54%
Increase in ascites	3	13%

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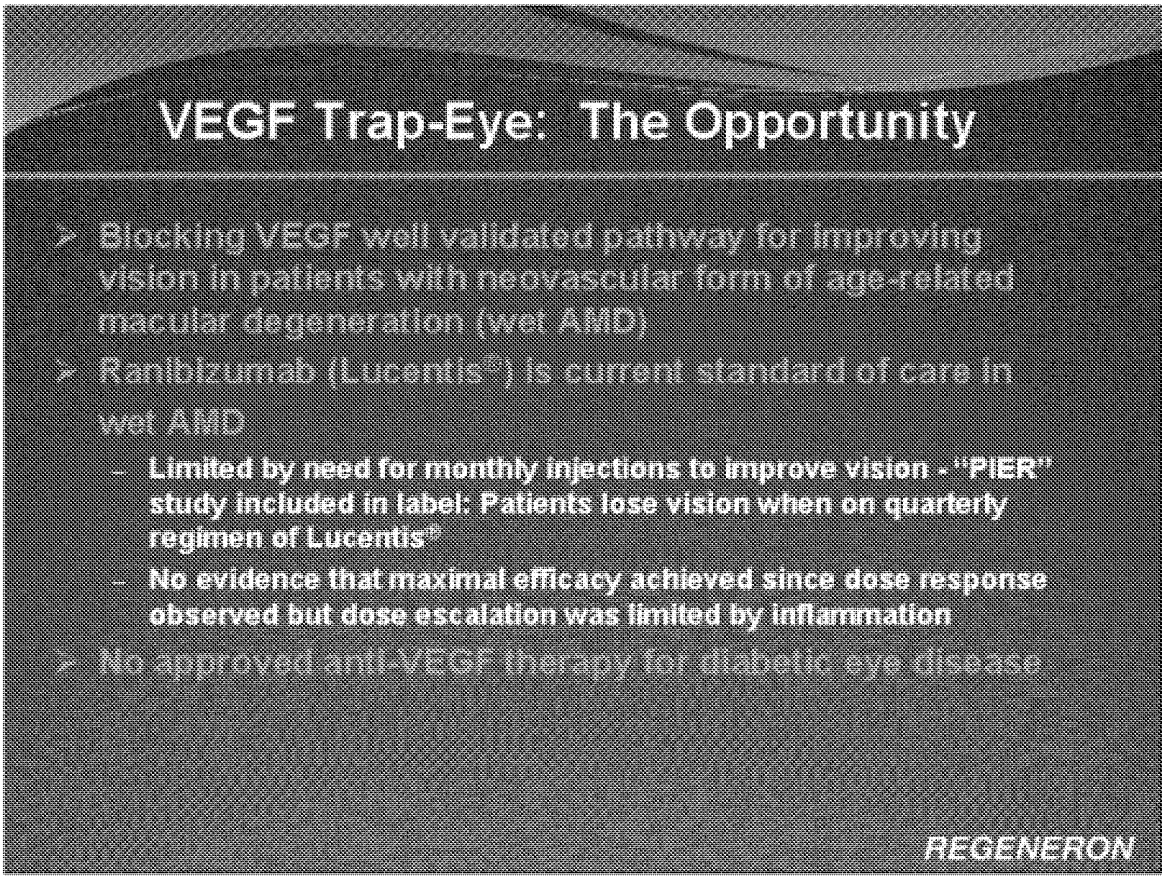
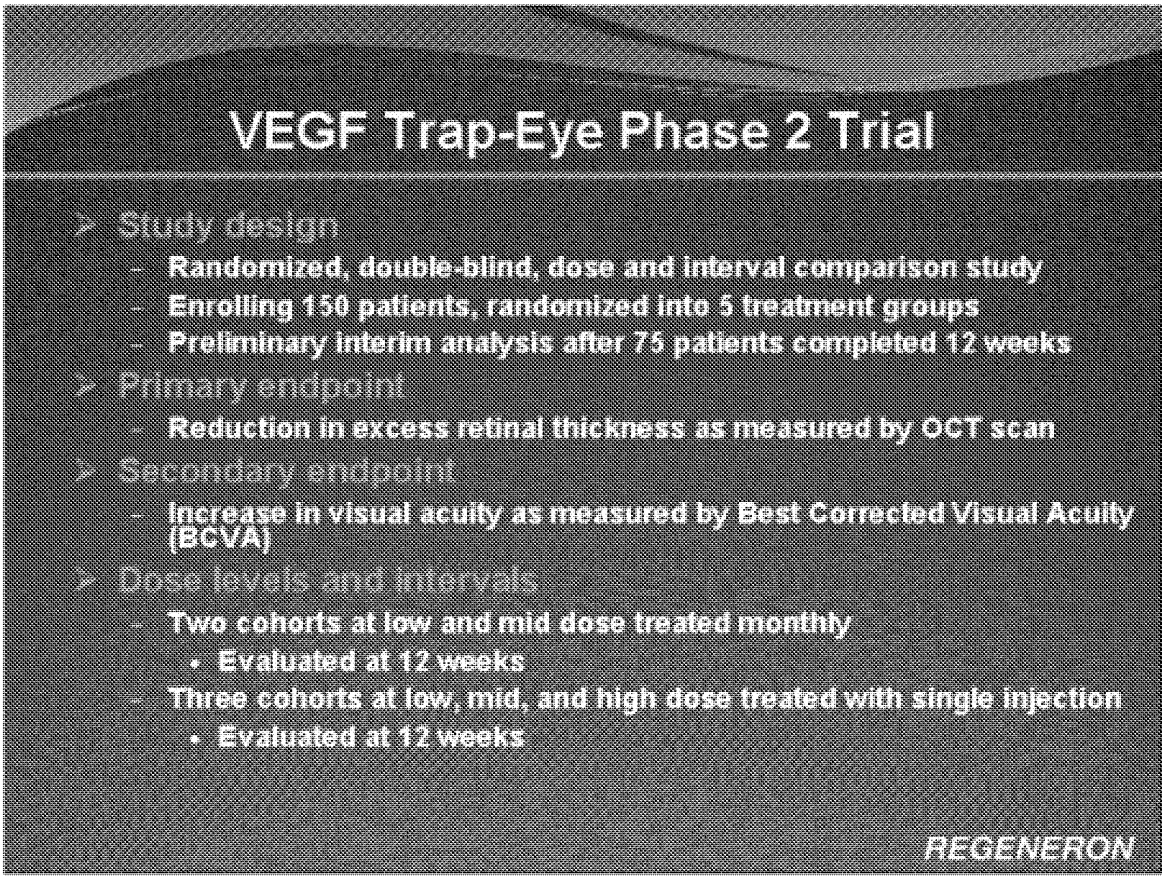
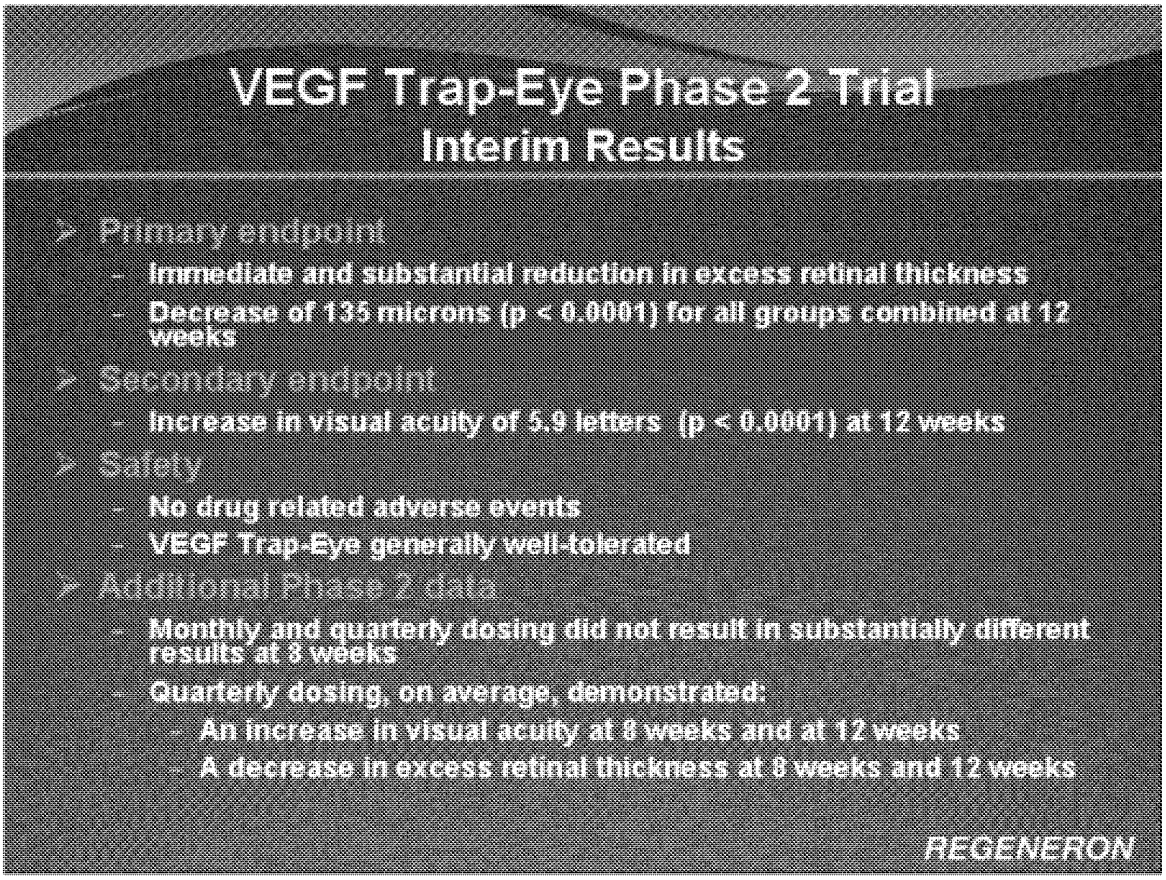
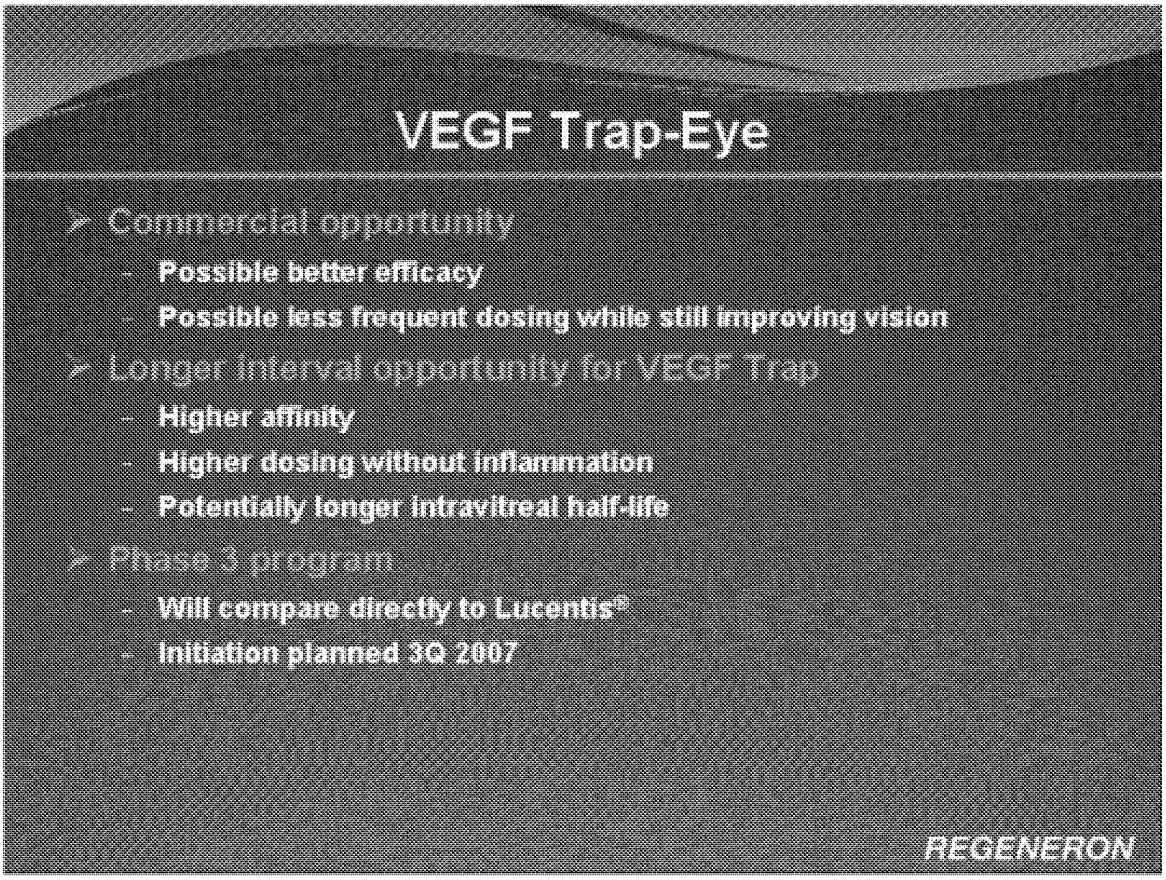
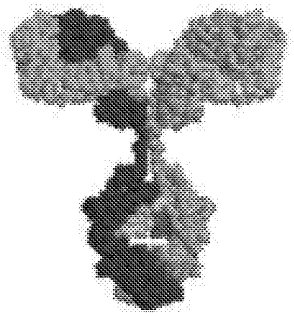

VEGF Trap-Eye: The Opportunity
Blocking VEGF well validated pathway for improving vision in patients with neovascular form of age-related macular degeneration (wet AMD)
Ranibizumab (Lucentis®) is current standard of care in wet AMD
Limited by need for monthly injections to improve vision - "PIER" study included in label: Patients lose vision when on quarterly regimen of Lucentis®
No evidence that maximal efficacy achieved since dose response observed but dose escalation was limited by inflammation
No approved anti-VEGF therapy for diabetic eye disease
REGENERON


VEGF Trap-Eye Phase 2 Trial
Study design
Randomized, double-blind, dose and interval comparison study
Enrolling 150 patients, randomized into 5 treatment groups
Preliminary interim analysis after 75 patients completed 12 weeks
Primary endpoint
Reduction in excess retinal thickness as measured by OCT scan
Secondary endpoint
Increase in visual acuity as measured by Best Corrected Visual Acuity (BCVA)
Dose levels and intervals
Two cohorts at low and mid dose treated monthly
Evaluated at 12 weeks
Three cohorts at low, mid, and high dose treated with single injection
Evaluated at 12 weeks
REGENERON


VEGF Trap-Eye Phase 2 Trial
Interim Results
Primary endpoint
Immediate and substantial reduction in excess retinal thickness
Decrease of 135 microns (p < 0.0001) for all groups combined at 12 weeks
Secondary endpoint
Increase in visual acuity of 5.9 letters (p < 0.0001) at 12 weeks
Safety
No drug related adverse events
VEGF Trap-Eye generally well-tolerated
Additional Phase 2 data
Monthly and quarterly dosing did not result in substantially different results at 8 weeks
Quarterly dosing, on average, demonstrated:
An increase in visual acuity at 8 weeks and at 12 weeks
A decrease in excess retinal thickness at 8 weeks and 12 weeks
REGENERON


VEGF Trap-Eye
Commercial opportunity
Possible better efficacy
Possible less frequent dosing while still improving vision
Longer interval opportunity for VEGF Trap
Higher affinity
Higher dosing without inflammation
Potentially longer intravitreal half-life
Phase 3 program
Will compare directly to Lucentis®
Initiation planned 3Q 2007
REGENERON

Future Pipeline:
Human Monoclonal Antibodies

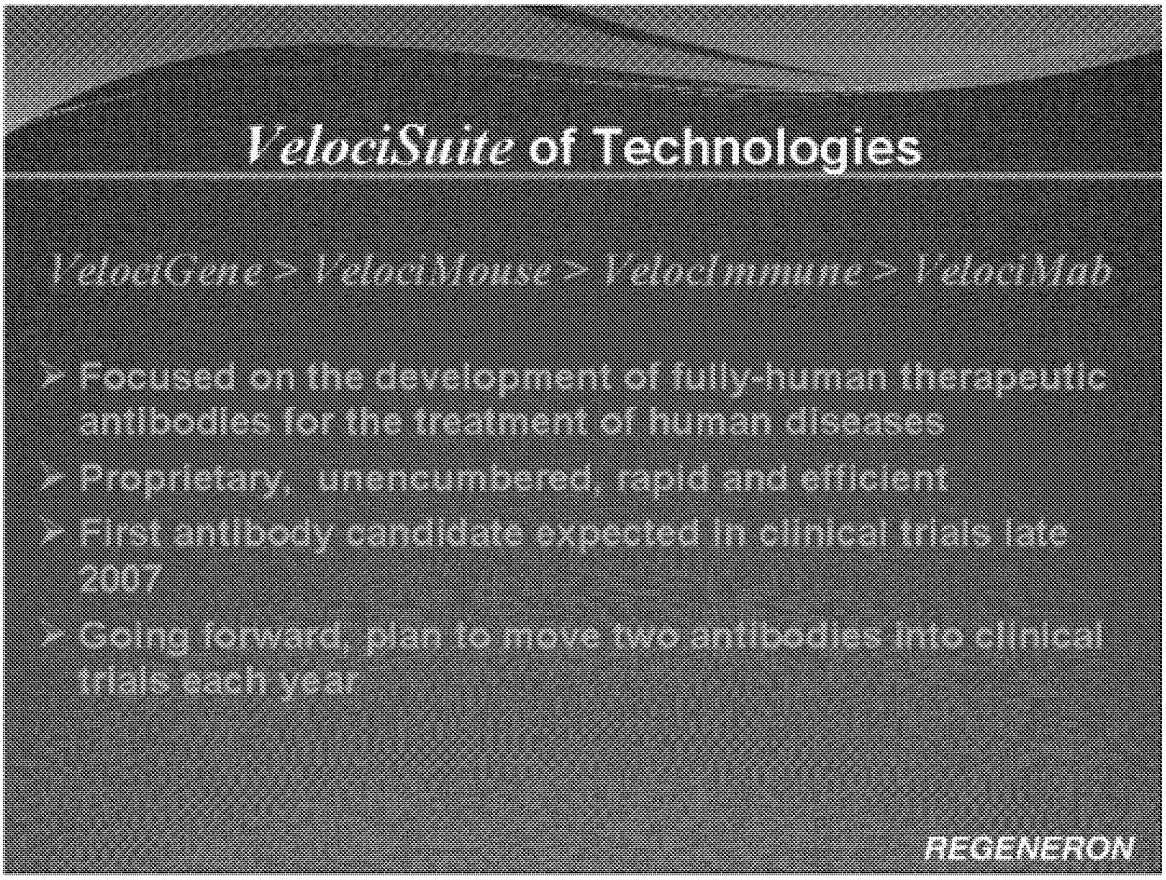


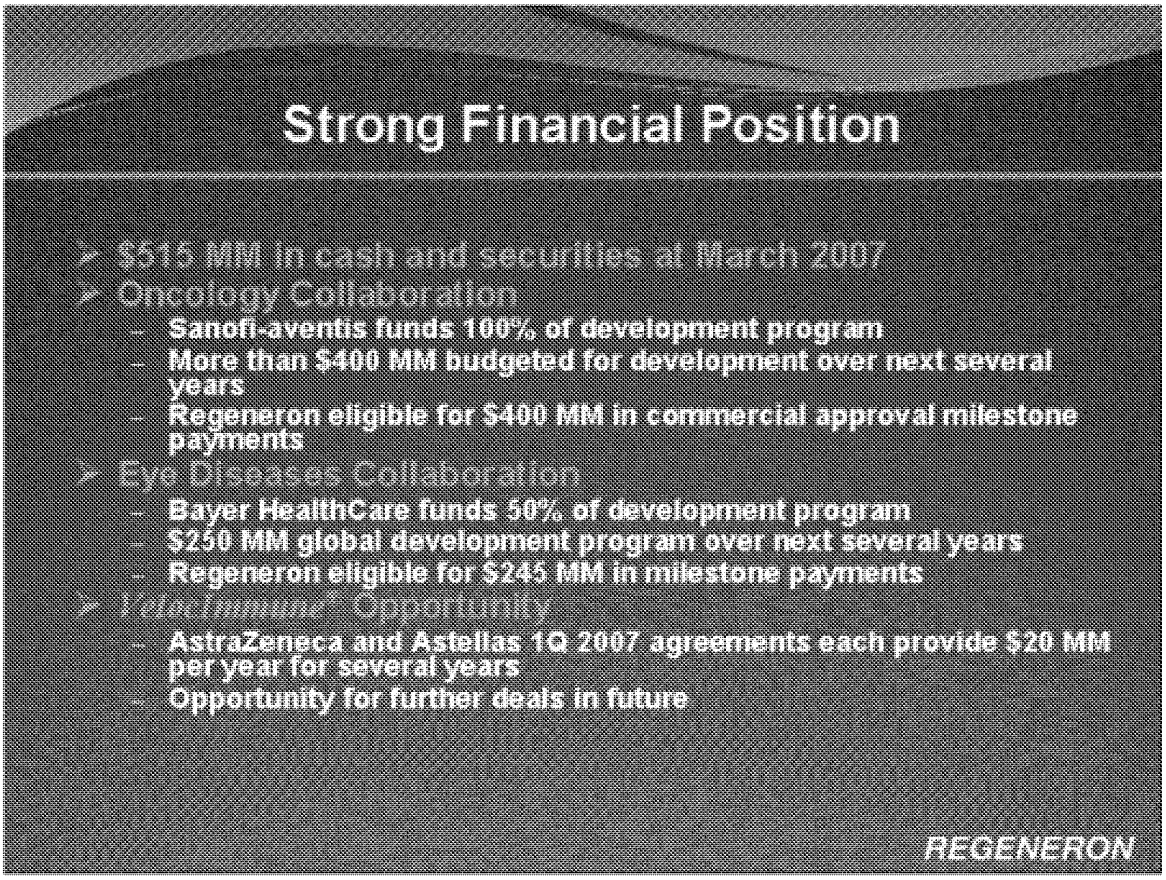
VelocImmune®

Regeneron's proprietary and breakthrough approach to discovering fully human monoclonal antibodies

- **Produces wide variety of high affinity antibodies against target**
- **Overcomes problem in antibody development that human MAb mice have compromised immune functions**
- **Synergizes with Regeneron's proprietary approach to cell line development and large-scale manufacturing capacity (10,000 liter GMP facility)**
- **Applicable to both validated and novel targets**

REGENERON


VelociSuite of Technologies
VelociGene > VelociMouse > VelocImmune > VelociMab
Focused on the development of fully-human therapeutic antibodies for the treatment of human diseases
Proprietary, unencumbered, rapid and efficient
First antibody candidate expected in clinical trials late 2007
Going forward, plan to move two antibodies into clinical trials each year
REGENERON


Strong Financial Position
$515 MM in cash and securities at March 2007
Oncology Collaboration
Sanofi-aventis funds 100% of development program
More than $400 MM budgeted for development over next several years
Regeneron eligible for $400 MM in commercial approval milestone payments
Eye Diseases Collaboration
Bayer HealthCare funds 50% of development program
$250 MM global development program over next several years
Regeneron eligible for $245 MM in milestone payments
VelocImmune® Opportunity
AstraZeneca and Astellas 1Q 2007 agreements each provide $20 MM per year for several years
Opportunity for further deals in future
REGENERON

REGENERON

Annual Meeting of Shareholders
June 8, 2007

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Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 10/1/2007

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934

Date of Report (Date of earliest event reported): October 1, 2007

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	000-19034	133444607
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On October 1, 2007, Regeneron issued a press release announcing positive results from the full analysis of the primary 12-week endpoint of a Phase 2 study evaluating the VEGF Trap-Eye in the neovascular form of age-related macular degeneration (wet AMD). A copy of this press release is attached as Exhibit 99(a) to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Press Release dated October 1, 2007.

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Dated: October 1, 2007

By: /s/ Stuart Kolinski
Stuart Kolinski
Senior Vice President and General Counsel

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Exhibit Index

Number	Description
99 (a)	Press Release dated October 1, 2007.

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FOR IMMEDIATE RELEASE

Regeneron Announces Positive Primary Endpoint Results from a Phase 2 Study of VEGF Trap-Eye in Age-related Macular Degeneration

Data presented at Retina Society Conference in Boston

Tarrytown, NY (October 1, 2007) — Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) and development partner, Bayer HealthCare AG (NYSE:BAY) of Leverkusen, Germany, today announced positive results from the full analysis of the primary 12-week endpoint of a Phase 2 study evaluating the VEGF Trap-Eye in the neovascular form of age-related macular degeneration (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 percent at baseline to 1.6 percent 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 percent at baseline to 49.2 percent at 16 weeks. These findings were presented at the Retina Society Conference in Boston, MA. The data reported at the meeting are available on the Regeneron website (www.regeneron.com on the Events Page, under the Investor Relations heading).

In this double-masked, prospective, randomized, multi-center Phase 2 trial, 157 patients were randomized to five groups and treated with the VEGF Trap-Eye in one eye. Two groups received monthly doses of 0.5 or 2.0 milligrams (mg) of VEGF Trap-Eye and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg of VEGF Trap-Eye (at baseline and week 12). Patients were monitored for safety, retinal thickness, and visual acuity. All five dose groups showed an improvement in retinal thickness and an increase in mean letters read versus baseline at all time points through week 12. There were no drug-related ocular or systemic serious adverse events (SAE) reported. Treatment with the VEGF Trap-Eye was

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generally well tolerated. The most common adverse events were those typically associated with intravitreal injections.

Preliminary week 16 results showed that retinal thickness for all groups combined continued to improve with a mean decrease of 159 microns versus baseline ($p<0.0001$). The mean change from baseline in visual acuity also continued to improve (all groups combined, increase of 6.6 letters versus baseline, $p<0.0001$). Patients receiving monthly doses of the VEGF Trap-Eye, either 0.5 or 2 mg, achieved mean decreases in retinal thickness of 160 and 183 microns, respectively, and mean improvements in visual acuity of 9.3 and 10 letters, respectively, at week 16. While quarterly dosing improved retinal thickness and visual acuity versus baseline at 12 and 16 weeks, the effect was not as robust as with monthly dosing. A single 2-mg dose maintained similar effect on visual acuity as 2 mg dosed monthly out to eight weeks (5.8 vs. 6.2 letters gained at 8 weeks, respectively). The table below summarizes preliminary 16-week results for patients in each dosing arm of the study.

"We are particularly encouraged by the decrease, following monthly treatment, in the proportion of patients with vision at the legally blind level of 20/200 or worse, as well as the proportion of patients whose vision improved to 20/40 or better," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "Our large Phase 3 program will help us determine the full impact of the VEGF Trap-Eye on visual acuity in these patient populations with significant unmet clinical needs."

"These results reaffirm the decision to study both the 0.5 mg and 2 mg monthly doses in the Phase 3 program," stated Jeffrey Heier, M.D., a clinical ophthalmologist at Ophthalmic Consultants of Boston, a primary investigator in the Phase 2 study, and chair of the steering committee for the Phase 3 VIEW 1 trial. "The quarterly dosing arms seemed to sustain their effect on visual acuity out to eight weeks, providing the rationale for exploring an eight-week dosing schedule in the Phase 3 program. Further improvement in visual acuity and dosing convenience continue to represent major unmet medical needs in the treatment of wet AMD."

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VEGF Trap Dose:	0.5 mg q4wk (n=32)	2 mg q4wk (n=31)	0.5 mg q12wk (n=32)	2 mg q12wk (n=31)	4 mg q12wk (n=31)
Retinal thickness (mean decrease in microns) at 16 wks	160	183	135	107	210
Visual acuity (mean letters gained) at 16 wks	9.3	10.0	5.6	4.3	3.9
% of patients who gained 15 or more letters at 16 wks	25%	39%	22%	19%	10%
% of patients with 20/40 vision or better:					
-At Baseline	16%	23%	22%	10%	16%
-At Week 16	44%	55%	31%	36%	32%
% of patients with 20/200 vision or less:					
-At Baseline	19%	10%	9%	7%	19%
-At Week 16	3%	0%	13%	7%	13%

About the Phase 3 Program in Wet AMD

Regeneron and Bayer HealthCare AG initiated a Phase 3 global development program for the VEGF Trap-Eye in wet AMD in August of this year. In the first Phase 3 trial, the companies will evaluate the VEGF Trap-Eye using four- and eight-week dosing intervals in direct comparison with ranibizumab (Lucentis®, a registered trademark of Genentech, Inc.) administered every four weeks according to its label. The Phase 3 wet AMD study is currently being enrolled. The companies are collaborating on the global development of the VEGF Trap-Eye for the treatment of wet AMD, diabetic eye diseases, and other eye 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. Regeneron maintains exclusive rights in the United States.

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About the VEGF Trap-Eye
Vascular endothelial growth factor (VEGF) is a naturally occurring protein in the body whose normal role is to trigger formation of new blood vessels (angiogenesis) to support the growth of the body's tissues and organs. It has also been associated with the abnormal growth and fragility of new blood vessels in the eye, which lead to the development of wet AMD. The VEGF Trap-Eye is a fully human, soluble VEGF receptor fusion protein that binds all forms of VEGF-A along with the related placental growth factor (PlGF). The VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. Blockade of VEGF, which can prevent abnormal blood vessel formation and vascular leak, has proven beneficial in the treatment of wet AMD and a VEGF inhibitor, ranibizumab, has been approved for treatment of patients with this condition.

About Wet AMD
Age-related macular degeneration (AMD) is a leading cause of acquired blindness. Macular degeneration is diagnosed as either dry (nonexudative) or wet (exudative). In wet AMD, new blood vessels grow beneath the retina and leak blood and fluid. This leakage causes disruption and dysfunction of the retina creating blind spots in central vision, and it can account for blindness in wet AMD patients. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

About Regeneron Pharmaceuticals
Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates for the potential treatment of cancer, eye diseases, and inflammatory diseases and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's worldwide web site at www.regeneron.com

Forward Looking Statement — Regeneron
This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-Q for

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the quarter ended June 30, 2007. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

# # #

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Laura Lindsay
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Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 11/6/2007

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 6, 2007

REGENERON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

New York	000-19034	13-3444607
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On November 6, 2007, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended September 30, 2007. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated November 6, 2007.

SIGNATURES

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 hereunto duly authorized.

Date: November 6, 2007

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski
Name: Stuart Kolinski
Title: Senior Vice President and General Counsel

Exhibit Index

Number	Description
99.1	Press Release dated November 6, 2007.

Exhibit 99.1

FOR IMMEDIATE RELEASE

Regeneron Reports Third Quarter Financial and Operating Results

Tarrytown, New York (November 6, 2007) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the third quarter of 2007. The Company reported a net loss of $35.8 million, or $0.54 per share (basic and diluted), for the third quarter of 2007 compared with a net loss of $27.4 million, or $0.48 per share (basic and diluted), for the third quarter of 2006. The Company reported a net loss of $92.5 million, or $1.40 per share (basic and diluted), for the nine months ended September 30, 2007 compared with a net loss of $71.4 million, or $1.25 per share (basic and diluted), for the same period in 2006.

At September 30, 2007, cash, restricted cash, and marketable securities totaled $497.3 million compared with $522.9 million at December 31, 2006. In the first quarter of 2007, the Company entered into non-exclusive license agreements with AstraZeneca UK Limited and Astellas Pharma Inc. with respect to the Company's *VelocImmune*® technology for generating human monoclonal antibody product candidates, as described below. In connection with these agreements, AstraZeneca and Astellas each made an up-front payment to the Company of $20.0 million in February and April 2007, respectively. In August 2007, the Company received a $20.0 million milestone payment from Bayer HealthCare LLC following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in the neovascular form of age-related macular degeneration (wet AMD).

The Company's $200.0 million of convertible notes, which bear interest at 5.5 percent per annum, mature in October 2008.

Current Business Highlights
Regeneron is currently focused on three late-stage clinical development programs: rilonacept (IL-1 Trap) in various inflammatory indications, aflibercept (VEGF Trap) in oncology in collaboration with the sanofi-aventis Group, and the VEGF Trap-Eye in eye diseases in collaboration with Bayer HealthCare. The Company is also developing its pipeline of preclinical antibody candidates discovered utilizing its *VelocImmune* technology.

Regeneron achieved the following milestones in the third quarter of 2007:

- FDA acceptance of the BLA submission for rilonacept for CAPS.

- Reported positive results from the Phase 2 trial for the VEGF Trap-Eye in wet AMD.
- Initiated a study in the Phase 3 program of the VEGF Trap-Eye in wet AMD.
- Received a milestone payment of $20.0 million from Bayer HealthCare upon initiation of the Phase 3 program in wet AMD.
- Initiated the Phase 3 oncology program for aflibercept (VEGF Trap) in combination with standard chemotherapy regimens.
- Completed enrollment of 200 patients in the Phase 2 single-agent aflibercept (VEGF Trap) study in advanced ovarian cancer.
- Reported positive results in an exploratory proof-of-concept trial of rilonacept in patients with gout.
- Initiated a Phase 2 safety and efficacy trial of rilonacept in gout patients.

During the fourth quarter of 2007, Regeneron expects to achieve the following key milestones:

- Report extended safety results for rilonacept in CAPS patients at the American College of Rheumatology (ACR) Annual Meeting in November 2007.
- Initiate a clinical trial of rilonacept in a third indication.
- Complete preparatory work for initiating the second Phase 3 trial for the VEGF Trap-Eye in wet AMD.
- Initiate two additional trials in the Phase 3 oncology program for aflibercept (VEGF Trap) in combination with standard chemotherapy regimens.
- Initiate a clinical trial testing the Company's first human monoclonal antibody product candidate.

Rilonacept — Inflammatory Diseases

The Company announced in August that the FDA had granted priority review status to the BLA for rilonacept (IL-1 Trap) for the long-term treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). CAPS is a group of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome. The FDA has previously granted Orphan Drug status and Fast Track designation to rilonacept for the treatment of CAPS. Rilonacept has also received Orphan Drug designation in the European Union for the treatment of CAPS. In November 2007, the Company announced that it received notification from the FDA that the action date for the FDA's priority review of the BLA for rilonacept had been extended three months to February 29, 2008.

The Company reported positive results from an exploratory proof-of-concept study of rilonacept in ten patients with chronic active gout. In those patients, treatment with rilonacept 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 percent ($p=0.025$) during the first two weeks of active treatment and reduced 56 percent ($p<0.004$) after six weeks of active treatment. In this study, in which safety was the primary endpoint measure, treatment with rilonacept

was generally well-tolerated. Regeneron has initiated a Phase 2 safety and efficacy trial of rilonacept in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy used to control the disease.

Regeneron is evaluating the potential use of rilonacept in other indications in which IL-1 may play a role. The Company plans to initiate an exploratory proof-of-concept study of rilonacept in the treatment of anemia associated with chronic inflammation before the end of 2007.

Aflibercept (VEGF Trap) — Oncology

In August 2007, Regeneron and sanofi-aventis announced the initiation of the first two Phase 3 trials that combine aflibercept with standard chemotherapy regimens. One trial will evaluate aflibercept in combination with docetaxel/prednisone in patients with 1st line metastatic androgen independent prostate cancer. The other trial will evaluate aflibercept in combination with docetaxel in patients with 2nd line metastatic non-small cell lung cancer. In both trials, aflibercept is being combined with the current standard of chemotherapy care for the stated development stage of the cancer type.

The companies plan to initiate Phase 3 trials in colorectal cancer and pancreatic cancer this quarter. In addition, currently underway or scheduled to begin are more than 10 studies to be 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.

VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a specially purified and formulated form of the VEGF Trap for use in intraocular applications. Regeneron and Bayer HealthCare initiated a Phase 3 global development program of the VEGF Trap-Eye in wet AMD in the third quarter of 2007. The 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. The 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. Regeneron and Bayer HealthCare plan to initiate a second Phase 3 trial in wet AMD in the first quarter of 2008. This second trial will be conducted primarily in the European Union and other parts of the world outside the U.S.

This quarter, the companies announced positive results of the Phase 2 trial of 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, $p<0.0001$). 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 percent at baseline to 1.6 percent 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 percent at baseline to 49.2 percent at 16 weeks.

Regeneron and Bayer HealthCare are collaborating on the global development of the VEGF Trap-Eye for the treatment of wet AMD, diabetic eye diseases, and other eye 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. Regeneron maintains exclusive rights to the VEGF Trap-Eye in the United States.

Monoclonal Antibodies

VelocImmune, Regeneron's novel technology for producing fully human monoclonal antibodies, is part of the Company's suite of proprietary, inter-related technology platforms that are designed to provide Regeneron with its next generation of therapeutic candidates. Regeneron plans to move its first new antibody product candidate into clinical trials this quarter. The Company plans to advance at least two additional antibody product candidates into human clinical trials each year, beginning in 2008.

Earlier this year, Regeneron entered into non-exclusive license agreements with AstraZeneca and Astellas that will allow those companies to utilize *VelocImmune* technology in their internal research programs to discover human monoclonal antibody product candidates. Each of those companies made a $20.0 million up-front, non-refundable payment and will make up to five additional annual payments of $20.0 million, subject to the ability to terminate the agreement after making the first three additional payments. Upon commercialization of any antibody products discovered utilizing *VelocImmune*, the licensees will pay to Regeneron a mid-single-digit royalty on product sales.

Financial Results

Revenue

Regeneron's total revenue increased to $22.3 million in the third quarter of 2007 from $15.6 million in the same quarter of 2006 and to $60.3 million for the first nine months of 2007 from $53.1 million for the same period of 2006. Contract research and development revenue in the first nine months of 2007 and 2006 principally related to the Company's aflibercept collaboration with sanofi-aventis in cancer indications. Contract manufacturing revenue in 2006 related to Regeneron's long-term manufacturing agreement with Merck & Co., Inc., which expired in October 2006. Technology licensing revenue in the first nine months of 2007 related to the Company's license agreements with AstraZeneca and Astellas.

Regeneron recognized contract research and development revenue of $9.2 million in the third quarter of 2007 and $34.5 million for the first nine months of 2007 related to the Company's collaboration with sanofi-aventis, compared with $10.0 million and $38.7 million, respectively, for the same periods of 2006. Contract research and development revenue from the sanofi-aventis collaboration consisted of reimbursement of aflibercept development expenses plus recognition of amounts related to $105.0 million of previously received and deferred up-front, non-refundable payments. Reimbursement of expenses was $7.0 million in both the third quarter of 2007 and 2006. In the first nine months of 2007, reimbursement of expenses decreased to $27.8 million from $29.6 million in the same period of 2006, principally because costs related to the Company's manufacture of aflibercept clinical supplies were lower in 2007. With respect to the up-front payments from sanofi-aventis, $2.2 million was recognized in the third quarter of 2007 compared to $3.0 million in the same quarter of 2006, and $6.7 million was recognized in the first nine months of 2007 compared to $9.1 million in the same period of 2006.

Sanofi-aventis also incurs aflibercept development expenses directly and these expenses are increasing because of the growing number of clinical trials sanofi-aventis is overseeing in the aflibercept oncology program. During the term of the collaboration, sanofi-aventis pays 100 percent of agreed-upon aflibercept development expenses incurred by both companies. Following commercialization of an aflibercept product by the collaboration, Regeneron, from its 50 percent share of aflibercept profits, will reimburse sanofi-aventis for 50 percent of aflibercept development expenses previously paid by sanofi-aventis.

Contract research and development revenue also includes $2.2 million in the third quarter of 2007 and $4.5 million for the first nine months of 2007, compared to $0.1 million for the same periods of 2006, in connection with the Company's five-year grant from the National Institutes of Health (NIH), which was awarded to the Company in September 2006 as part of the NIH's Knockout Mouse Project.

In connection with the Company's license agreements with AstraZeneca and Astellas, both of the $20.0 million non-refundable, up-front payments received in February and April 2007, respectively, were deferred and are being recognized as revenue ratably over

approximately the first year of each agreement. In the third quarter and for the first nine months of 2007, the Company recognized $10.0 million and $18.4 million, respectively, of technology licensing revenue related to these agreements.

Bayer HealthCare Collaboration

In October 2006, the Company entered into a collaboration with Bayer HealthCare for the development and commercialization of the VEGF Trap-Eye outside the United States, and received a $75.0 million up-front, non-refundable payment. In 2007, 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 $50.0 million will be shared equally; Regeneron is solely responsible for the next $40.0 million; over $90.0 million will be shared equally. Through September 30, 2007, reimbursements from Bayer HealthCare of our VEGF Trap-Eye development expenses totaled $12.9 million. In addition, as described above, the Company received a $20.0 million milestone payment from Bayer HealthCare in August 2007. All payments received or receivable from Bayer HealthCare through September 30, 2007, totaling $107.9 million, have been fully deferred and included in deferred revenue for financial statement purposes.

Expenses

Total operating expenses for the third quarter of 2007 were $61.0 million, 39 percent higher than the same period in 2006, and $163.2 million for the first nine months of 2007, 28 percent higher than the same period in 2006. Operating expenses included non-cash compensation expense related to employee stock option awards (Stock Option Expense) of $7.0 million in the third quarter of 2007 and $20.5 million for the first nine months of 2007, compared with $4.7 million and $13.2 million, respectively, for the same periods of 2006. The increase in total Stock Option Expense in 2007 was primarily due to the higher fair market value of the Company's Common Stock on the date of annual employee option grants made by the Company in December 2006 in comparison to the fair market value of the Company's Common Stock on the dates of annual employee option grants made in recent prior years.

Research and development (R&D) expenses increased to $51.7 million in the third quarter of 2007 from $34.8 million in the comparable quarter of 2006, and to $136.8 million for the first nine months of 2007 from $101.3 million for the same period of 2006. In addition to the impact of Stock Option Expense, as described above, in the first nine months of 2007, the Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for the VEGF Trap-Eye and rilonacept, and development costs for new antibody candidates. These were partly offset by lower development expenses incurred by Regeneron for the aflibercept cancer program.

General and administrative (G&A) expenses increased to $9.3 million in the third quarter of 2007 from $6.0 million in the comparable quarter of 2006, and to $26.4 million in the first nine months of 2007 from $18.3 million in the same period of 2006. In addition to the impact of Stock Option Expense, as described above, in the first nine months of 2007,

the Company incurred higher G&A costs related to additional headcount and higher fees for various professional services.

Other Income
Investment income increased to $5.8 million in the third quarter of 2007 from $3.9 million in the comparable quarter of 2006, and to $19.4 million for the first nine months of 2007 from $11.0 million for the same period of 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 $174.6 million in net proceeds from the November 2006 public offering of 7.6 million shares of the Company's Common Stock.

About Regeneron Pharmaceuticals
Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, and has preclinical programs in other diseases and disorders.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2006 and Form 10-Q for the quarter ended June 30, 2007. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	September 30, 2007	December 31, 2006
ASSETS		
Cash, restricted cash, and marketable securities	$ 497,292	$ 522,859
Receivables	10,968	7,493
Property, plant, and equipment, net	49,358	49,353
Other assets	15,478	5,385
Total assets	$ 573,096	$ 585,090
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 27,872	$ 21,471
Deferred revenue	193,827	146,995
Notes payable	200,000	200,000
Stockholders' equity	151,397	216,624
Total liabilities and stockholders' equity	$ 573,096	$ 585,090

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2007	2006	2007	2006
Revenues				
Contract research and development	$ 12,311	$ 11,448	$ 41,873	$ 41,026
Contract manufacturing		4,176		12,075
Technology licensing	10,000		18,421	
	22,311	15,624	60,294	53,101
Expenses				
Research and development	51,689	34,808	136,788	101,290
Contract manufacturing		3,054		7,716
General and administrative	9,289	6,019	26,426	18,264
	60,978	43,881	163,214	127,270
Loss from operations	(38,667)	(28,257)	(102,920)	(74,169)
Other income (expense)				
Investment income	5,840	3,858	19,424	11,023
Interest expense	(3,011)	(3,011)	(9,033)	(9,033)
	2,829	847	10,391	1,990
Net loss before cumulative effect of a change in accounting principle	(35,838)	(27,410)	(92,529)	(72,179)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")				813
Net loss	$ (35,838)	$ (27,410)	$ (92,529)	$ (71,366)
Net loss per share amounts, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	$ (0.54)	$ (0.48)	$ (1.40)	$ (1.27)
Cumulative effect of adopting SFAS 123R				0.02
Net loss	$ (0.54)	$ (0.48)	$ (1.40)	$ (1.25)
Weighted average shares outstanding, basic and diluted	66,069	57,011	65,861	56,884

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Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 5/2/2008

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 2, 2008 (May 1, 2008)

REGENERON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

New York	000-19034	13-3444607
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 **Results of Operations and Financial Condition.**

On May 1, 2008, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 2008. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release dated May 1, 2008.

SIGNATURES

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 hereunto duly authorized.

Date: May 2, 2008

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski
Name: Stuart Kolinski
Title: Senior Vice President and General Counsel

Exhibit Index

Number	Description
99.1	Press Release dated May 1, 2008.

REGENERON

Exhibit 99.1

FOR IMMEDIATE RELEASE

Regeneron Reports First Quarter 2008 Financial and Operating Results

Tarrytown, New York (May 1, 2008) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the first quarter 2008. The Company reported a net loss of $11.6 million, or $0.15 per share (basic and diluted), for the first quarter of 2008 compared with a net loss of $29.9 million, or $0.46 per share (basic and diluted), for the first quarter of 2007.

At March 31, 2008, cash, restricted cash, and marketable securities totaled $827.9 million compared with $846.3 million at December 31, 2007. The Company's $200.0 million of convertible notes, which bear interest at 5.5 percent per annum, mature in October 2008.

Current Business Highlights

ARCALYST™ (rilonacept) — Inflammatory Diseases

The Company announced in February 2008 that it had received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST™ (rilonacept) Injection for Subcutaneous Use, an interleukin-1 blocker, 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. ARCALYST is the only therapy approved 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. In late March 2008, ARCALYST became available for prescription in the United States and the Company began making shipments of ARCALYST to its distributors. ARCALYST has also received Orphan Drug designation in the European Union for the treatment of CAPS.

A Phase 2 safety and efficacy trial of ARCALYST is underway in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy used to control gout. The Company is also evaluating the potential use of ARCALYST in other indications in which interleukin-1 (IL-1) may play a role.

Aflibercept (VEGF Trap) — Oncology

In their collaboration to develop aflibercept for the treatment of cancer, Regeneron and sanofi-aventis currently are enrolling patients in four Phase 3 trials that combine aflibercept with standard chemotherapy regimens. One trial is evaluating aflibercept as

a 2nd line treatment for metastatic colorectal cancer in combination with folinic acid, 5-FU, and irinotecan. A second trial is evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine. A third trial is evaluating aflibercept as a 1st line treatment for metastatic androgen independent prostate cancer in combination with docetaxel/prednisone. The fourth trial is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel. All four trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. In addition, more than 13 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.

VEGF Trap-Eye — Eye Diseases

VEGF Trap-Eye is a specially purified and formulated form of the VEGF Trap for use in intraocular applications. Regeneron and Bayer HealthCare initiated a Phase 3 global development program of VEGF Trap-Eye in the neovascular form of Age-related Macular Degeneration (wet AMD) in the third quarter of 2007. The first trial, known as VIEW 1 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), is comparing VEGF Trap-Eye and ranibizumab (Lucentis®, a registered trademark of Genentech, Inc.), an anti-angiogenic agent approved for use in wet AMD. The trial is evaluating dosing intervals of four and eight weeks for VEGF Trap-Eye, compared with ranibizumab dosed every four weeks according to its label. Bayer HealthCare is initiating a second Phase 3 trial of VEGF Trap-Eye in wet AMD in the European Union and other parts of the world outside the U.S.

In April 2008, Regeneron and Bayer HealthCare announced the 32-week endpoint results of a Phase 2 study evaluating VEGF Trap-Eye in wet AMD, which were presented at the 2008 Association for Research in Vision and Ophthalmology (ARVO) meeting in Fort Lauderdale, Florida. The analysis showed that VEGF Trap-Eye dosed on a PRN (as-needed) dosing schedule maintained the statistically significant gain in visual acuity achieved after an initial 12-week, fixed-dosing phase.

Study results showed that across all dose groups in the study population the 6.6 mean letter gain in visual acuity achieved versus baseline at the week 16 evaluation visit, following 12 weeks of fixed dosing, was maintained out to week 32 (a 6.7 mean letter gain versus baseline; $p< 0.0001$) using a PRN dosing schedule (where dosing frequency was determined by the physician's assessment of pre-specified criteria). The decrease in retinal thickness, an anatomical measure of treatment effect, achieved with a fixed-dose schedule was also maintained for all dose groups combined at week 32 (a 137 micron mean decrease versus baseline, $p<0.0001$).

Patients receiving monthly doses of VEGF Trap-Eye, either 0.5 or 2.0 mg, for 12 weeks followed by PRN dosing thereafter achieved mean improvements in visual acuity of 8.0 ($p<0.01$ versus baseline) and 10.1 letters ($p<0.0001$ versus baseline), respectively, and

mean decreases in retinal thickness of 141 (p<0.0001 versus baseline) and 162 microns (p<0.0001 versus baseline) at week 32, respectively.

After the last fixed-dose administration at week 12, patients from all dose groups combined required, on average, only one additional injection over the following 20 weeks to maintain the visual acuity gain established during the fixed-dosing period. Notably, 55 percent of the patients who received 2.0 mg monthly for 12 weeks did not require any additional treatment throughout the next 20-week PRN dosing period. Moreover, 97 percent of the patients who received 2.0 mg monthly for 12 weeks did not require re-dosing at the week 16 evaluation visit, indicating that an 8-week dosing schedule may be feasible.

Regeneron and Bayer HealthCare are collaborating on the global development of VEGF Trap-Eye for the treatment of wet AMD, diabetic eye diseases, and other eye 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. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

Monoclonal Antibodies

Regeneron and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune*® technology. The first therapeutic antibody to enter clinical development under the collaboration is REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis. A second antibody candidate, an antibody to Delta-like ligand-4 (Dll4), is slated to start clinical development in mid-2008. The Company and sanofi-aventis plan to advance two to three new antibodies into clinical development each year.

Financial Results

Revenue

Regeneron's total revenue increased to $56.4 million in the first quarter of 2008 from $15.8 million in the same period of 2007. Contract research and development revenue in the first quarter of 2008 principally related to the Company's aflibercept and antibody collaborations with sanofi-aventis and the Company's VEGF Trap-Eye collaboration with Bayer HealthCare. In the first quarter of 2007, contract research and development revenue primarily related to the Company's aflibercept collaboration with sanofi-aventis. Technology licensing revenue related to the Company's license agreements with AstraZeneca and Astellas.

Regeneron recognized contract research and development revenue of $13.8 million in the first quarter of 2008 related to the Company's aflibercept collaboration with sanofi-aventis, compared with $11.8 million in the same period of 2007. Contract research and development revenue from the collaboration consisted of reimbursement of aflibercept development expenses incurred by the Company plus recognition of amounts related to

$105.0 million of previously received and deferred non-refundable, up-front payments. Reimbursement of expenses increased to $11.7 million in the first quarter of 2008 from $9.6 million in the same period of 2007, principally due to higher costs related to the Company's manufacture of aflibercept clinical supplies and higher clinical development costs. With respect to the $105.0 million of up-front payments from sanofi-aventis, $2.1 million was recognized in the first quarter of 2008 compared to $2.2 million in the same period of 2007.

Sanofi-aventis also incurs aflibercept development expenses directly and these expenses are increasing because of the growing number of clinical trials sanofi-aventis is overseeing in the oncology program. During the term of the aflibercept collaboration, sanofi-aventis pays 100 percent of agreed-upon aflibercept development expenses incurred by both companies. Following commercialization of an aflibercept product, Regeneron, from its 50 percent share of aflibercept profits, will reimburse sanofi-aventis for 50 percent of aflibercept development expenses previously paid by sanofi-aventis.

Regeneron recognized contract research and development revenue of $21.9 million in the first quarter of 2008 related to the Company's antibody collaboration with sanofi-aventis. Contract research and development revenue from the antibody collaboration consisted of $15.1 million for reimbursement of the Company's expenses under the collaboration's discovery agreement, $4.2 million for reimbursement of the Company's REGN88 development expenses, and $2.6 million related to an $85.0 million non-refundable, up-front payment, which was deferred upon receipt in December 2007.

In connection with the Company's VEGF Trap-Eye collaboration with Bayer HealthCare, the Company received a $75.0 million non-refundable, up-front payment in October 2006 and a $20.0 million milestone payment in August 2007. Through September 30, 2007 all payments received from Bayer HealthCare, including the up-front and milestone payments and cost-sharing reimbursements were fully deferred and included in deferred revenue. In the fourth quarter of 2007, the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost sharing of the Company's VEGF Trap-Eye development expenses in the Company's Statement of Operations through a cumulative catch-up. The $75.0 million non-refundable, up-front license payment and $20.0 million milestone payment are being recognized as contract research and development revenue over the related estimated performance period. In periods when the Company recognizes VEGF Trap-Eye development expenses that it incurs under the collaboration, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that are 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 first quarter of 2008, the Company recorded $9.0 million of contract research and development revenue from Bayer HealthCare, consisting of $3.3 million related to the $75.0 million up-front licensing payment and the $20.0 million milestone payment and $5.7 million related to the portion of the Company's first quarter 2008 VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare.

Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that allow those companies to utilize *VelocImmune*® technology in their internal research programs to discover human monoclonal antibodies. Each company made a $20.0 million up-front, non-refundable payment in 2007 and will make up to five additional annual payments of $20.0 million, subject to the ability to terminate their agreements after making three additional payments. Upon receipt, these payments are deferred and are recognized as revenue ratably over approximately the ensuing year of each agreement. Regeneron will also receive a mid-single-digit royalty on sales of any antibodies discovered utilizing *VelocImmune*. In the first quarter of 2008 and 2007, the Company recognized $10.0 million and $2.1 million, respectively, of technology licensing revenue related to these agreements.

ARCALYST™ (rilonacept) Product Sales

In late March 2008, the Company shipped $0.8 million of ARCALYST to its distributors, which was fully deferred at March 31, 2008 and classified as deferred revenue in the Company's financial statements.

Expenses

Total operating expenses for the first quarter of 2008 were $72.3 million, 46 percent higher than the same period in 2007. Our average headcount increased to 714 in the first quarter of 2008 from 585 in the same period of 2007 primarily as a result of our expanding research and development activities directed toward preclinical and clinical development of product candidates, including ARCALYST™, aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88 and the Dll4 antibody).

Operating expenses included non-cash compensation expense related to employee stock option and restricted stock awards of $8.3 million and $6.6 million in the first quarters of 2008 and 2007, respectively.

Research and development (R&D) expenses increased to $61.3 million in the first quarter of 2008 from $41.2 million in the comparable quarter of 2007. The Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for VEGF Trap-Eye and ARCALYST, and costs related to manufacturing supplies of aflibercept, VEGF Trap-Eye, and the Dll4 antibody.

Selling, general, and administrative expenses increased to $11.0 million in the first quarter of 2008 from $8.2 million in the comparable period of 2007. In the first quarter of 2008, the Company incurred costs associated with the launch of ARCALYST. In addition, the Company incurred higher compensation expense and recruitment costs associated with expanding the Company's headcount, and higher legal fees related to general corporate matters.

Other Income

Investment income increased to $7.3 million in the first quarter of 2008 from $6.7 million in the comparable quarter of 2007. The increase in investment income resulted primarily from higher balances of cash and marketable securities, due primarily to receipts from sanofi-aventis of $312.0 million for the purchase of 12 million shares of the Company's Common Stock in December 2007 and the $85.0 million up-front payment related to the antibody collaboration, partially offset by lower effective interest rates in 2008.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST™ (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2007. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	March 31, 2008	December 31, 2007
ASSETS		
Cash, restricted cash, and marketable securities	$827,858	$ 846,279
Receivables	32,960	18,320
Property, plant, and equipment, net	58,419	58,304
Other assets	11,639	13,355
Total assets	$930,876	$ 936,258
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 30,314	$ 39,232
Deferred revenue	239,959	236,759
Notes payable	200,000	200,000
Stockholders' equity	460,603	460,267
Total liabilities and stockholders' equity	$930,876	$ 936,258

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended March 31, 2008	2007
Revenues		
Contract research and development	$ 46,383	$ 13,645
Technology licensing	10,000	2,143
	56,383	15,788
Expenses		
Research and development	61,270	41,235
Selling, general, and administrative	11,024	8,202
	72,294	49,437
Loss from operations	(15,911)	(33,649)
Other income (expense)		
Investment income	7,304	6,743
Interest expense	(3,011)	(3,011)
	4,293	3,732
Net loss	$(11,618)	$(29,917)
Net loss per share amounts, basic and diluted	$ (0.15)	$ (0.46)
Weighted average shares outstanding, basic and diluted	78,493	65,563

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 11/4/2008

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 4, 2008

REGENERON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

New York	000-19034	13-3444607
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 **Results of Operations and Financial Condition.**

On November 4, 2008, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended September 30, 2008. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release dated November 4, 2008.

SIGNATURES

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 hereunto duly authorized.

Date: November 4, 2008

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski
Name: Stuart Kolinski
Title: Senior Vice President and General Counsel

Exhibit Index

Number	Description
99.1	Press Release dated November 4, 2008.

REGENERON

Exhibit 99.1

For Immediate Release

Press Release

Regeneron Reports Third Quarter 2008 Financial and Operating Results

Tarrytown, New York (November 4, 2008) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the third quarter of 2008. The Company reported a net loss of $21.1 million, or $0.27 per share (basic and diluted), for the third quarter of 2008 compared with a net loss of $35.8 million, or $0.54 per share (basic and diluted), for the third quarter of 2007. The Company reported a net loss of $51.2 million, or $0.65 per share (basic and diluted), for the nine months ended September 30, 2008 compared with a net loss of $92.5 million, or $1.40 per share (basic and diluted), for the same period in 2007.

At September 30, 2008, cash, restricted cash, and marketable securities totaled $692.9 million compared with $846.3 million at December 31, 2007. At September 30, 2008, $117.5 million of the Company's convertible senior subordinated notes remained outstanding. These notes were repaid in full upon their maturity in October 2008.

Current Business Highlights

ARCALYST® (rilonacept) — Inflammatory Diseases

In February 2008, the Company 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. In March 2008, ARCALYST became available for prescription in the United States, and the Company began making shipments to our distributors and transitioning the patients who participated in the CAPS pivotal study from clinical study drug to commercial supplies. This transition has been mostly completed and the Company currently projects shipments of ARCALYST to its distributors to total approximately $10 million in 2008.

ARCALYST, an interleukin-1 (IL-1) blocker, 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. In July 2008, the Company submitted a Marketing Authorization Application (MAA) with the European Medicines Agency (EMEA) for ARCALYST for the treatment of CAPS in the European Union.

In September 2008, the Company 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 uric acid-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 rilonacept (p=0.0011), an 81 percent reduction. This was the primary endpoint of the study. All secondary endpoints also were met with statistical significance. Injection-site reaction was the most commonly reported adverse event with ARCALYST® (rilonacept) treatment and no serious drug-related adverse events were reported.

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.

The Company plans to initiate a Phase 3 clinical development program with ARCALYST in the first half of 2009 for both the prevention of gout flares in patients initiating urate-lowering drug therapy and in acute gout. The Company is also planning to initiate clinical studies of ARCALYST in other indications in which IL-1 may play a role.

Aflibercept (VEGF Trap) — Oncology

In their collaboration to develop aflibercept for the treatment of cancer, Regeneron and sanofi-aventis currently are enrolling patients in four Phase 3 trials that combine aflibercept with standard chemotherapy regimens. 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. In addition, a Phase 2 study of aflibercept in 1st line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin is expected to begin by the end of 2008.

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 more than 90 percent enrolled and patients continue to be enrolled in the study.

Multiple exploratory studies are being or will be 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.

VEGF Trap-Eye — Eye Diseases

VEGF Trap-Eye is a specially purified and formulated form of the VEGF Trap for use in intraocular applications. Regeneron and Bayer HealthCare are currently testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of Age-related Macular Degeneration (wet AMD). Regeneron and Bayer HealthCare are also developing VEGF Trap-Eye in diabetic macular edema (DME) and plan to initiate a Phase 2 study in patients with DME by early 2009.

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.

In September 2008, Regeneron and Bayer HealthCare announced the final 52-week endpoint results of a Phase 2 study evaluating VEGF Trap-Eye in wet AMD, which were presented at the 2008 Retina Society meeting in Scottsdale, Arizona. 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. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg for 12 weeks followed by PRN dosing 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.

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 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.

VEGF Trap-Eye was generally well tolerated in this Phase 2 study 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.

Monoclonal Antibodies

Regeneron and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune*® technology. The first therapeutic antibody to enter clinical development under the collaboration is REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis. The Company plans to file Investigational New Drug Applications (INDs) for an antibody to Delta-like ligand-4 (Dll4) by the end of 2008 and one additional antibody product candidate shortly thereafter. The Company and sanofi-aventis plan to advance an average of two to three new antibodies into clinical development each year.

In August 2008, the Company entered into a separate agreement with sanofi-aventis to use its *VelociGene*® technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay the Company 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, outside of the scope of the antibody collaboration between the Company and sanofi-aventis.

In September 2008, the Company entered into an agreement under the Company's Academic *VelocImmune*®Investigators Program (Academic VIP) that will provide researchers at Columbia University Medical Center with access to the *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. The Company has an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products.

Financial Results

Revenues

Total revenues increased to $65.6 million in the third quarter of 2008 from $22.3 million in the comparable quarter of 2007, and to $182.6 million in the first nine months of 2008 from $60.3 million in the same period in 2007. The Company's revenue was comprised of contract research and development revenue, technology licensing revenue, and net product sales.

Contract Research and Development Revenue

Contract research and development revenue relates primarily to the Company's aflibercept and antibody collaborations with sanofi-aventis and the Company's VEGF Trap-Eye collaboration with Bayer HealthCare. Contract research and development revenue for the three and nine months ended September 30, 2008 and 2007, consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	**2008**	**2007**	**2008**	**2007**
Contract research & development revenue				
Sanofi-aventis	$ 42.0	$ 9.2	$ 116.3	$ 34.5
Bayer HealthCare	9.0		28.2	
Other	1.9	3.1	5.4	7.4
Total contract research & development revenue	$ 52.9	$ 12.3	$ 149.9	$ 41.9

For the three and nine months ended September 30, 2008, contract research and development revenue from sanofi-aventis consisted of the following:

(In millions)	Three months ended September 30, 2008	Three months ended September 30, 2007	Nine months ended September 30, 2008	Nine months ended September 30, 2007
Aflibercept:				
Regeneron expense reimbursement	$ 7.3	$ 7.0	$ 29.3	$ 27.8
Recognition of deferred revenue related to up-front payments	2.1	2.2	6.2	6.7
Total aflibercept	9.4	9.2	35.5	34.5
Antibody:				
Regeneron expense reimbursement	29.5		72.4	
Recognition of deferred revenue related to up-front payment	2.6		7.9	
Other	0.5		0.5	
Total antibody	32.6		80.8	
Total sanofi-aventis contract research & development revenue	$ 42.0	$ 9.2	$ 116.3	$ 34.5

Contract research and development revenue from sanofi-aventis included 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.

In connection with the aflibercept collaboration, sanofi-aventis also incurs aflibercept development expenses directly and these expenses have increased in 2008 because of the four Phase 3 clinical trials that sanofi-aventis is overseeing in the oncology program that commenced in the third and fourth quarters of 2007. During the term of the aflibercept collaboration, sanofi-aventis pays 100 percent of agreed-upon aflibercept development expenses incurred by both companies. Following commercialization of an aflibercept product, Regeneron, from its 50 percent share of aflibercept profits, will reimburse sanofi-aventis for 50 percent of aflibercept development expenses previously paid by sanofi-aventis.

For the three and nine months ended September 30, 2008, contract research and development revenue from Bayer HealthCare consisted of the following:

(In millions)	Three months ended September 30, 2008	Nine months ended September 30, 2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 5.7	$ 18.3
Recognition of deferred revenue related to up-front and milestone payments	3.3	9.9
Total Bayer HealthCare contract & research development revenue	$ 9.0	$ 28.2

In connection with the Company's VEGF Trap-Eye collaboration with Bayer HealthCare, the Company received a $75.0 million non-refundable, up-front payment in October 2006 and a $20.0 million milestone payment in August 2007. Through September 30, 2007 all payments received from Bayer HealthCare, including the up-front and milestone payments and cost-sharing reimbursements, were fully deferred and included in deferred revenue. In the fourth quarter of

2007, the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost sharing of the Company's VEGF Trap-Eye development expenses in the Company's Statement of Operations through a cumulative catch-up. The $75.0 million non-refundable, up-front license payment and $20.0 million milestone payment are being recognized as contract research and development revenue over the related estimated performance period. In periods when the Company recognizes VEGF Trap-Eye development expenses that it 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.

Technology Licensing Revenue

Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that allow those companies to utilize *VelocImmune*® technology in their internal research programs to discover human monoclonal antibodies. Each company made a $20.0 million up-front, non-refundable payment in 2007 and agreed to make up to five additional annual payments of $20.0 million, subject to the ability to terminate their agreements after making three additional payments. Upon receipt, these payments are deferred and are recognized as revenue ratably over approximately the ensuing year of each agreement. Regeneron will also receive a mid-single-digit royalty on sales of any antibodies discovered utilizing *VelocImmune*.

Net Product Sales

In March 2008, the Company commenced shipping ARCALYST® (rilonacept) to its distributors. In the third quarter of 2008, the Company began recognizing product sales revenue for ARCALYST and recorded $2.7 million of product sales, net of related discounts, rebates, and distributor fees. At September 30, 2008, $3.8 million of ARCALYST net product sales was included in deferred revenue in the Company's financial statements.

Expenses

Total operating expenses for the third quarter of 2008 were $85.5 million, 40 percent higher than the same period in 2007, and $237.9 million for the first nine months of 2008, 46 percent higher than the same period in 2007. Average headcount increased to 851 in the third quarter of 2008 from 639 in the same period of 2007 and increased to 778 for the first nine months of 2008 from 614 in the same period of 2007, due primarily to the Company's expanding research and development activities principally in connection with the Company's antibody collaboration with sanofi-aventis.

Operating expenses included non-cash compensation expense related to employee stock option and restricted stock awards of $8.2 million in the third quarter of 2008 and $24.7 million for the first nine months of 2008, compared with $7.0 million and $20.5 million, respectively, for the same periods of 2007.

Research and development (R&D) expenses increased to $73.8 million in the third quarter of 2008 from $51.7 million in the comparable quarter of 2007, and to $201.7 million in the first nine months of 2008 from $136.8 million in the same period of 2007. The Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for VEGF Trap-Eye, ARCALYST, and REGN88, costs related to manufacturing supplies of VEGF Trap-Eye and monoclonal antibodies (including REGN88), and facilities-related costs to support the Company's expanded research and development activities. Also, as described above, commencing in the fourth quarter of 2007, the Company began recognizing as additional R&D expense the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse.

Selling, general, and administrative (SG&A) expenses increased to $11.4 million in the third quarter of 2008 from $9.3 million in the comparable quarter of 2007, and to $35.9 million in the first nine months of 2008 from $26.4 million in the same period of 2007. In the first nine months of 2008, the Company incurred SG&A costs associated with the launch of ARCALYST® (rilonacept). In addition, the Company incurred higher compensation expense and recruitment costs associated with expanding the Company's SG&A headcount, higher professional fees related to various general corporate matters, and higher SG&A facility-related costs.

Other Income and Expense

Investment income decreased to $3.7 million in the third quarter of 2008 from $5.8 million in the comparable quarter of 2007 and to $15.5 million in the first nine months of 2008 compared to $19.4 million in the first nine months of 2007 due primarily to lower yields on the Company's cash and marketable securities.

During the first nine months of 2008, the Company repurchased $82.5 million in principal amount of its 5.5 percent Convertible Senior Subordinated Notes. In connection with the repurchased notes, the Company recognized a $0.9 million loss on early extinguishment of debt. The remaining $117.5 million of these notes were repaid in full upon their maturity in October 2008.

Income Tax Expense

In the third quarter of 2008, the Company incurred and paid income tax expense, consisting primarily of alternative minimum tax, of $3.1 million, which resulted from the utilization of certain net operating loss carry-forwards for tax purposes that would otherwise have expired over the next several years.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2007 and Form 10-Q for the quarter ended June 30, 2008. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	September 30, 2008	December 31, 2007
ASSETS		
Cash, restricted cash, and marketable securities	$ 692,861	$ 846,279
Receivables	42,206	18,320
Property, plant, and equipment, net	72,825	58,304
Other assets	17,999	13,355
Total assets	$ 825,891	$ 936,258
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 44,772	$ 39,232
Deferred revenue	226,683	236,759
Notes payable	117,503	200,000
Stockholders' equity	436,933	460,267
Total liabilities and stockholders' equity	$ 825,891	$ 936,258

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2008	2007	2008	2007
Revenues				
Contract research and development	$ 52,878	$ 12,311	$149,914	$ 41,873
Technology licensing	10,000	10,000	30,000	18,421
Net product sales	2,706		2,706	
	65,584	22,311	182,620	60,294
Expenses				
Research and development	73,855	51,689	201,702	136,788
Selling, general, and administrative	11,368	9,289	35,857	26,426
Cost of goods sold	292		292	
	85,515	60,978	237,851	163,214
Loss from operations	(19,931)	(38,667)	(55,231)	(102,920)
Other income (expense)				
Investment income	3,674	5,840	15,513	19,424
Interest expense	(1,772)	(3,011)	(7,457)	(9,033)
Loss on early extinguishment of debt	(7)		(938)	
	1,895	2,829	7,118	10,391
Net loss before income tax expense	(18,036)	(35,838)	(48,113)	(92,529)
Income tax expense	3,079		3,079	
Net loss	$(21,115)	$(35,838)	$ (51,192)	$ (92,529)
Net loss per share amounts, basic and diluted	$ (0.27)	$ (0.54)	$ (0.65)	$ (1.40)
Weighted average shares outstanding, basic and diluted	78,937	66,069	78,706	65,861

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 1/9/2009

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934

Date of Report (Date of earliest event reported): January 9, 2009

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	000-19034	13-3444607
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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EX-99.A: SLIDES

Item 7.01 Regulation FD Disclosure

Attached as Exhibit 99(a) are slides that Regeneron Pharmaceuticals, Inc. intends to use in conjunction with meetings with investors at the J.P. Morgan 27th Annual Healthcare Conference in San Francisco on January 12-15, 2009.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Slides that Regeneron Pharmaceuticals, Inc. intends to use in conjunction with meetings with investors at the J.P. Morgan 27th Annual Healthcare Conference in San Francisco on January 12-15, 2009.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 4988

Samsung Bioepis Exhibit 1017, pg. 4988

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Dated: January 9, 2009

By: /s/ Stuart Kolinski
Stuart Kolinski
Senior Vice President and General Counsel

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Samsung Bioepis Exhibit 1017, pg. 4990

REGENERON
27th Annual J. P. Morgan
Healthcare Conference
January 2009

Safe Harbor Statement

Except for historical information, the matters contained in this presentation may constitute forward-looking statements that involve risks and uncertainties, including uncertainties related to product development and clinical trials, unforeseen safety issues resulting from the administration of products in patients, uncertainties related to the need for regulatory and other government approvals, risks related to third party patents and proprietary technology, the need for additional capital, uncertainty of market acceptance of Regeneron's product candidates, the receipt of future payments, the continuation of business partnerships, and additional risks detailed from time to time in Regeneron's filings with the Securities and Exchange Commission (SEC). Please refer to Regeneron's recent Forms 10-K, 10-Q, and 8-K for additional information on the uncertainties and risk factors related to our business.

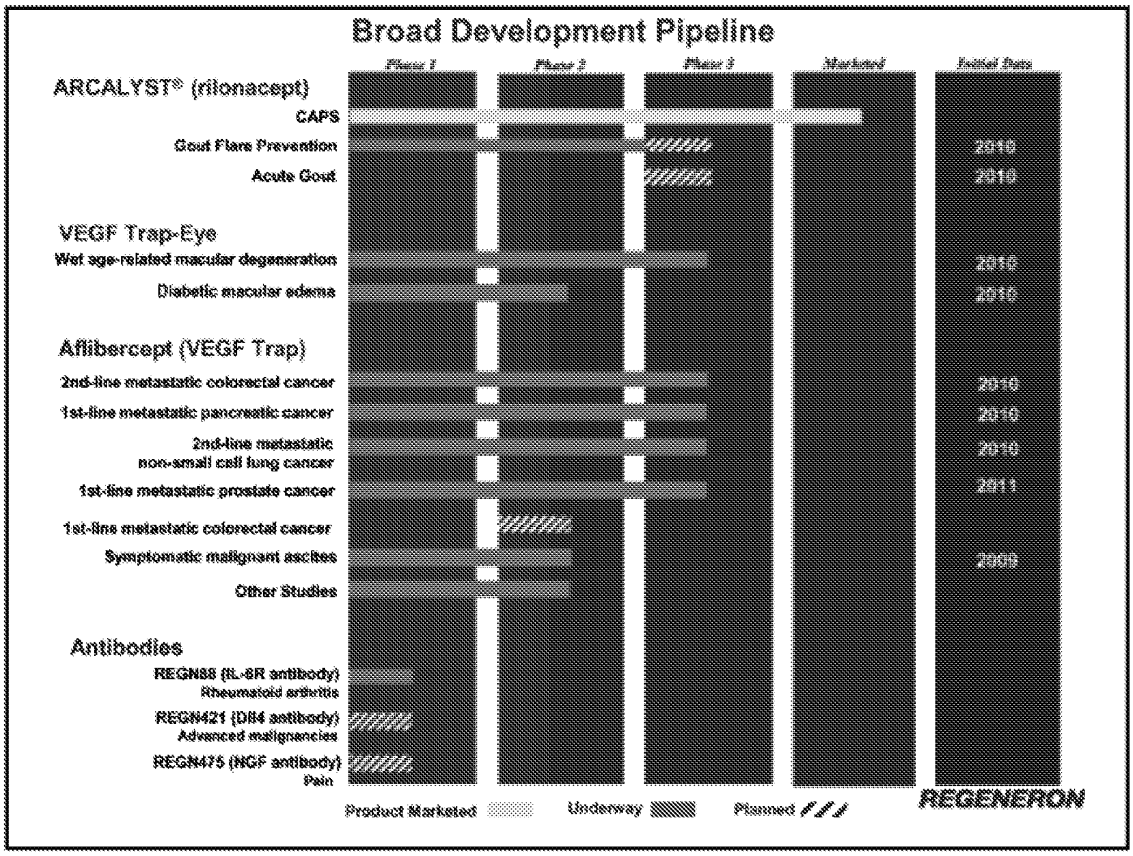
Because forward-looking statements involve risks and uncertainties, actual results may differ materially from current results expected by Regeneron. Regeneron is providing this information as of the original date of this presentation and expressly disclaims any duty to update any information contained in these materials.

REGENERON

Regeneron Overview

- **ARCALYST® (rilonacept) marketed for treatment of orphan auto-inflammatory disease (CAPS)**
- **Broad Development Pipeline – 9 Phase 3 trials by mid-2009**
  - **Oncology** – Symptomatic malignant ascites data in mid-2009; 4 Phase 3 programs enrolling patients
  - **Eye Disease** – Phase 3 program in wet AMD planned to complete enrollment this year; Phase 2 program in DME initiated
  - **Inflammatory Disease** – Phase 3 program in gout to begin 1Q09
- ***VelocImmune®* Antibody Platform**
  - One Phase 1 trial in rheumatoid arthritis plus 2 INDs filed December 2008
  - Target 2-3 new antibody INDs per year
- **Strong Financial Position**
  - 2008 year-end cash and securities of ~$528MM; no debt
  - Significant funding from collaborations with sanofi-aventis and Bayer HealthCare

REGENERON


Broad Development Pipeline
Phase 1
Phase 2
Phase 3
Marketed
Initial Data
ARCALYST® (rilonacept)
CAPS
Gout Flare Prevention
Acute Gout
2010
2010
VEGF Trap-Eye
Wet age-related macular degeneration
Diabetic macular edema
2010
2010
Aflibercept (VEGF Trap)
2nd-line metastatic colorectal cancer
1st-line metastatic pancreatic cancer
2nd-line metastatic non-small cell lung cancer
1st-line metastatic prostate cancer
1st-line metastatic colorectal cancer
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Other Studies
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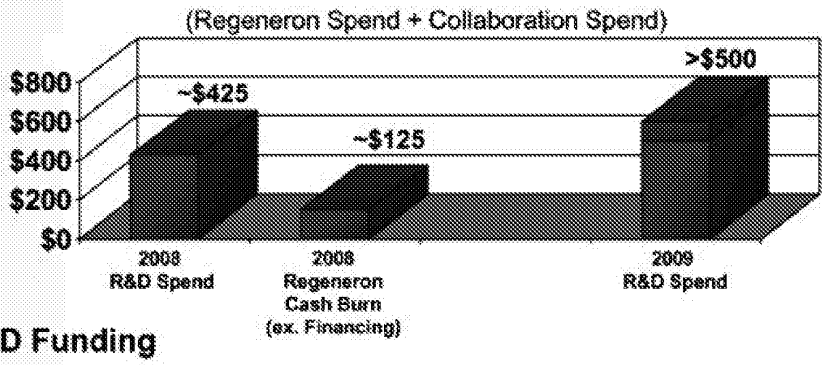
Antibodies
REGN88 (IL-6R antibody) Rheumatoid arthritis
REGN421 (Dll4 antibody) Advanced malignancies
REGN475 (NGF antibody) Pain
Product Marketed
Underway
Planned
REGENERON

R&D Investment Leverage

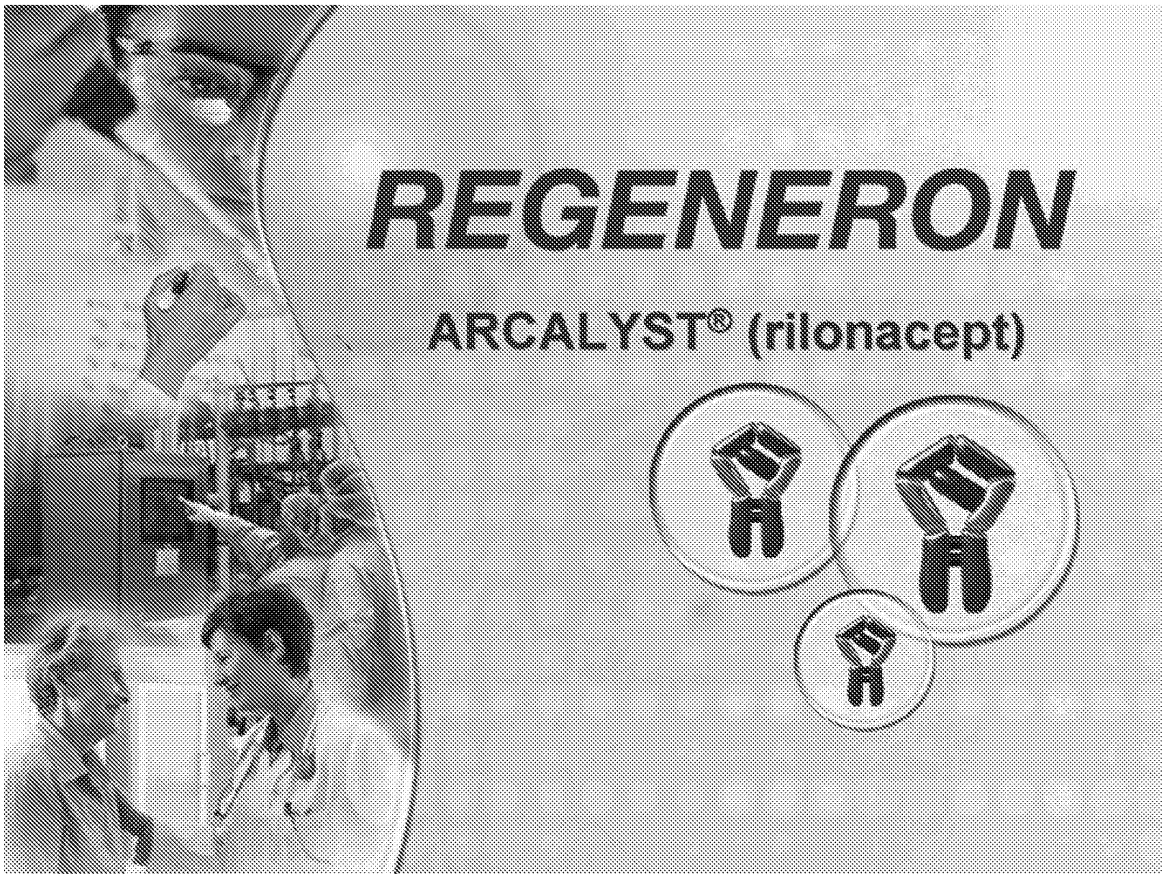
Total Estimated R&D Spend on Regeneron Programs ($MM)



- **R&D Funding**
  - Aflibercept: 100% funded by sanofi-aventis*
  - Antibody Discovery: $75MM in 2008 and $100MM/year in 2009-12 funded by sanofi-aventis
  - Antibody Development: 100% funded by sanofi-aventis*
  - VEGF Trap-Eye: 50% funded by Bayer HealthCare*

* 50% repayment from profits

REGENERON


REGENERON
ARCALYST® (rilonacept)

ARCALYST® (rilonacept)
Approved and Launched in 2008

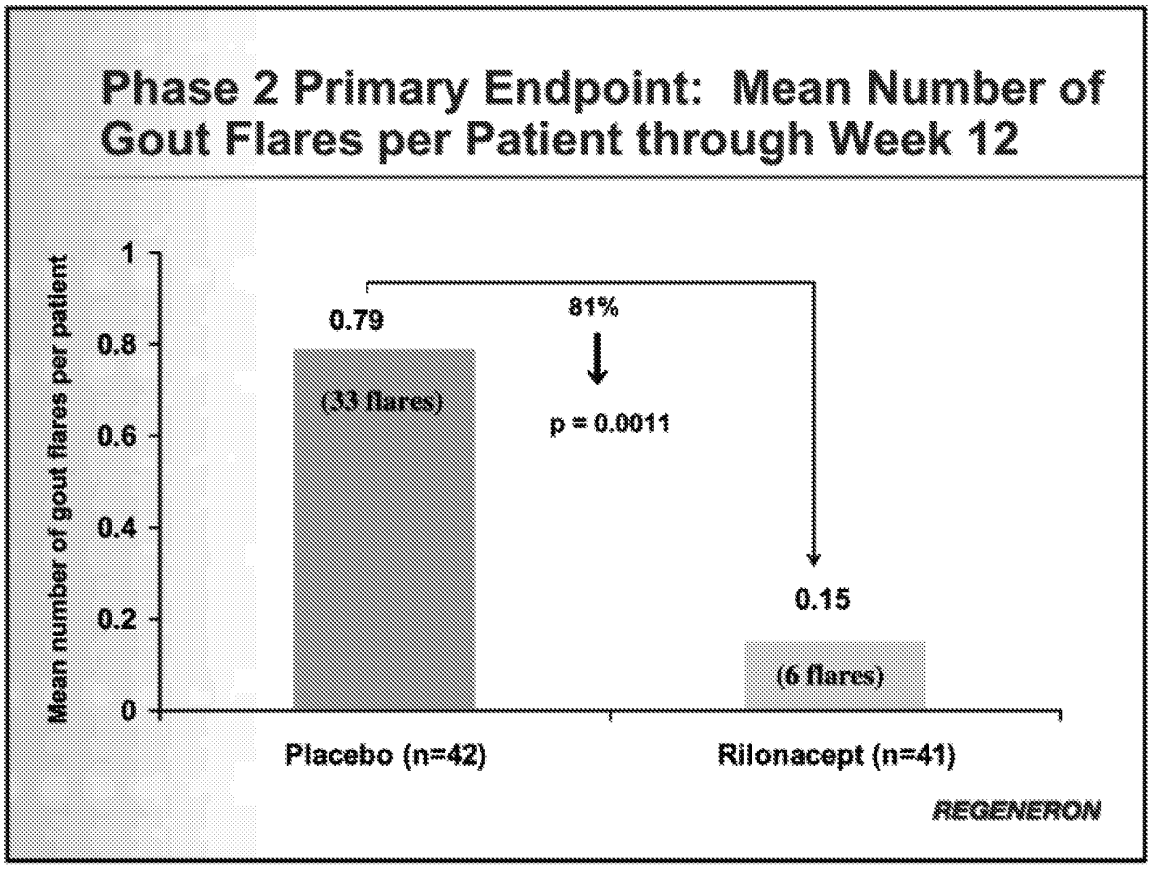
- **ARCALYST® (rilonacept) is the only therapy approved for treatment of Cryopyrin-Associated Periodic Syndromes (CAPS)**
  - Rare, inherited, auto-inflammatory diseases
    - Familial Cold Auto-inflammatory Syndrome (FCAS)
    - Muckle-Wells Syndrome (MWS)
  - Approved for adults and children age 12 and older
  - Full prescribing information available at regeneron.com
- **Patients with CAPS experience ongoing lifelong symptoms**
  - Intermittent, debilitating exacerbations or flares can be triggered at any time by exposure to cooling temperatures
  - Symptoms include rash, fever/chills, joint pain, eye redness/pain and fatigue
  - Patients often adopt a compromised lifestyle
- **2008 shipments ~$11MM; 2009 estimate ~$20-24MM**

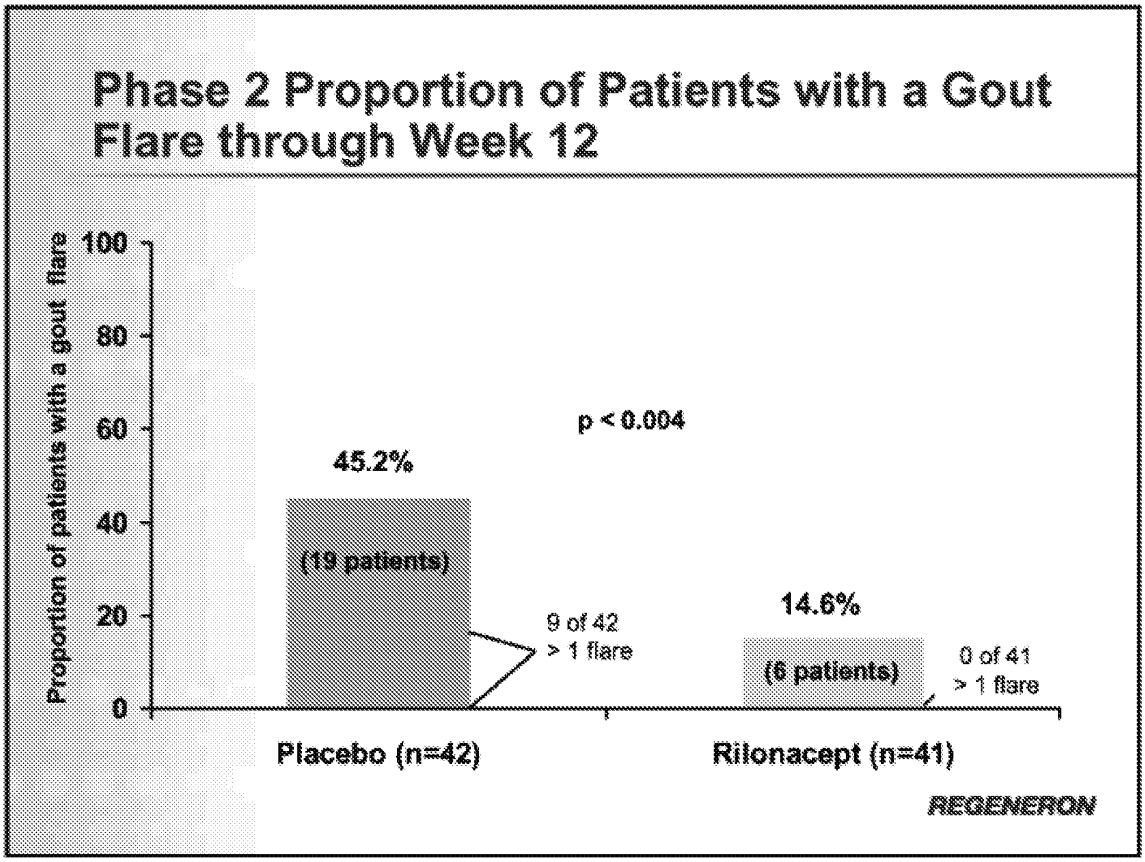
REGENERON

Rilonacept in Gout

- **Unmet medical need**
  - 1% of US population suffers from gout – one of the most painful rheumatic diseases
  - > 750,000 gout patients start on allopurinol each year to lower uric acid levels; during first months of therapy many experience acute flares of joint pain and inflammation
  - 1.4MM people treated for acute gout attacks each year – 20% in hospital ER's
- **Phase 2 trial completed in prevention of allopurinol-induced gout flares**
  - **Met primary and secondary endpoints**
  - **No serious drug-related adverse events**

REGENERON


Phase 2 Primary Endpoint: Mean Number of Gout Flares per Patient through Week 12
Mean number of gout flares per patient
1
0.8
0.6
0.4
0.2
0
0.79
(33 flares)
81%
p = 0.0011
0.15
(6 flares)
Placebo (n=42)
Rilonacept (n=41)
REGENERON


Phase 2 Proportion of Patients with a Gout Flare through Week 12
Proportion of patients with a gout flare
100
80
60
40
20
0
p < 0.004
45.2%
(19 patients)
9 of 42
> 1 flare
14.6%
(6 patients)
0 of 41
> 1 flare
Placebo (n=42)
Rilonacept (n=41)
REGENERON

Phase 3 Rilonacept Program in Gout

- Gout flares induced by urate-lowering drugs
  - Two studies: rilonacept vs. placebo
- Acute gout
  - rilonacept vs. NSAIDs vs. NSAIDs plus rilonacept
- Safety study
- Program to start 1Q09

REGENERON

REGENERON
Aflibercept (VEGF Trap)

Aflibercept (VEGF Trap)
Phase 3 Oncology Program

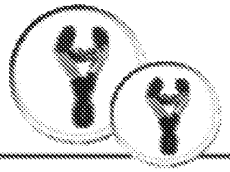
Partnered with sanofi-aventis

- All studies approximately 1/3 enrolled
- Each study monitored by Independent Data Monitoring Committee

	Total Number of Patients to be Enrolled	Initial Data Expected
VELOUR study: 2nd line metastatic colorectal cancer (+ folinic acid, 5-FU & irinotecan)	1200	2010
VANILLA study: 1st line metastatic pancreatic cancer (+ gemcitabine)	630	2010
VITAL study: 2nd line non-small cell lung cancer (+ Taxotere®)	900	2010
VENICE study: 1st line metastatic hormone resistant prostate cancer (+ Taxotere®)	1240	2011

REGENERON

Aflibercept Single-Agent Phase 2 - SMA



- **Symptomatic Malignant Ascites (SMA) in Advanced Ovarian Cancer (AOC)**
  - Condition in which fluid containing cancer cells collects in the abdomen
  - Treated by paracentesis – procedure in which fluid is directly drained from the abdomen
- **Randomized, placebo-controlled study**
  - **Fully enrolled**
  - **Data expected mid-2009**

REGENERON

Mylan Exhibit 1017
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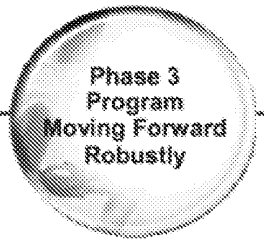
Samsung Bioepis Exhibit 1017, pg. 5004

Aflibercept Summary



- **SMA target enrollment reached**
  - Data expected mid-2009
- **4 Phase 3 studies approximately 1/3 enrolled**
  - Initial data expected 2010
- **Additional studies**
  - Colorectal cancer Phase 2 study: First line treatment with FOLFOX6+/- aflibercept recruiting patients
- **Over 1600 patients treated with aflibercept in clinical trials**

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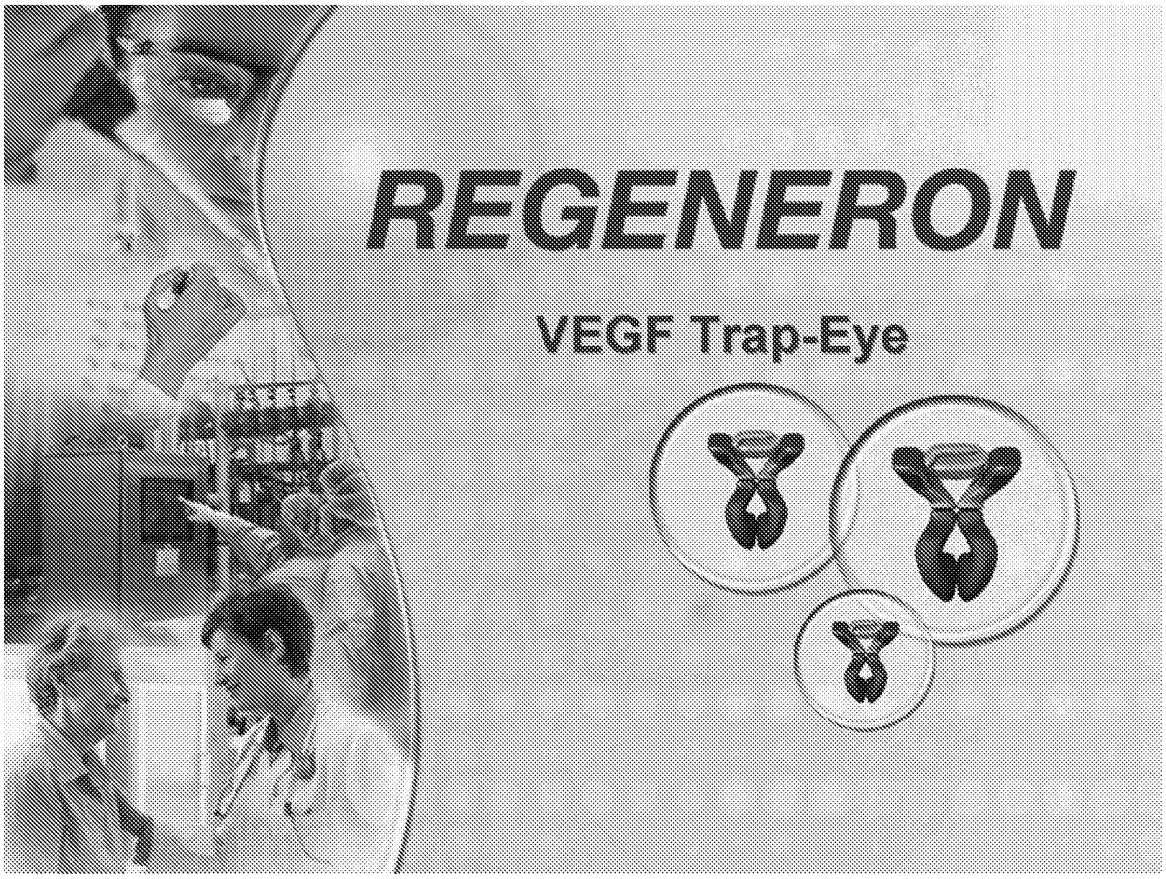
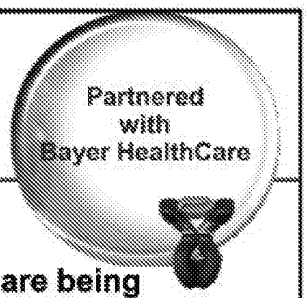

REGENERON
VEGF Trap-Eye

VEGF Trap-Eye – The Opportunity



- **Potential differentiation relative to standard of care being explored in patients with neovascular form of age-related macular degeneration (wet AMD)**
  - Possible visual acuity gains
  - Possible less frequent dosing with similar gain in vision
  - Potential maintenance of visual acuity gain with as-needed dosing
- **Development Program**
  - Phase 2 study in wet AMD completed
  - Two Phase 3 studies in wet AMD enrolling patients
  - Phase 2 study in diabetic macular edema (DME) initiated in 4Q08

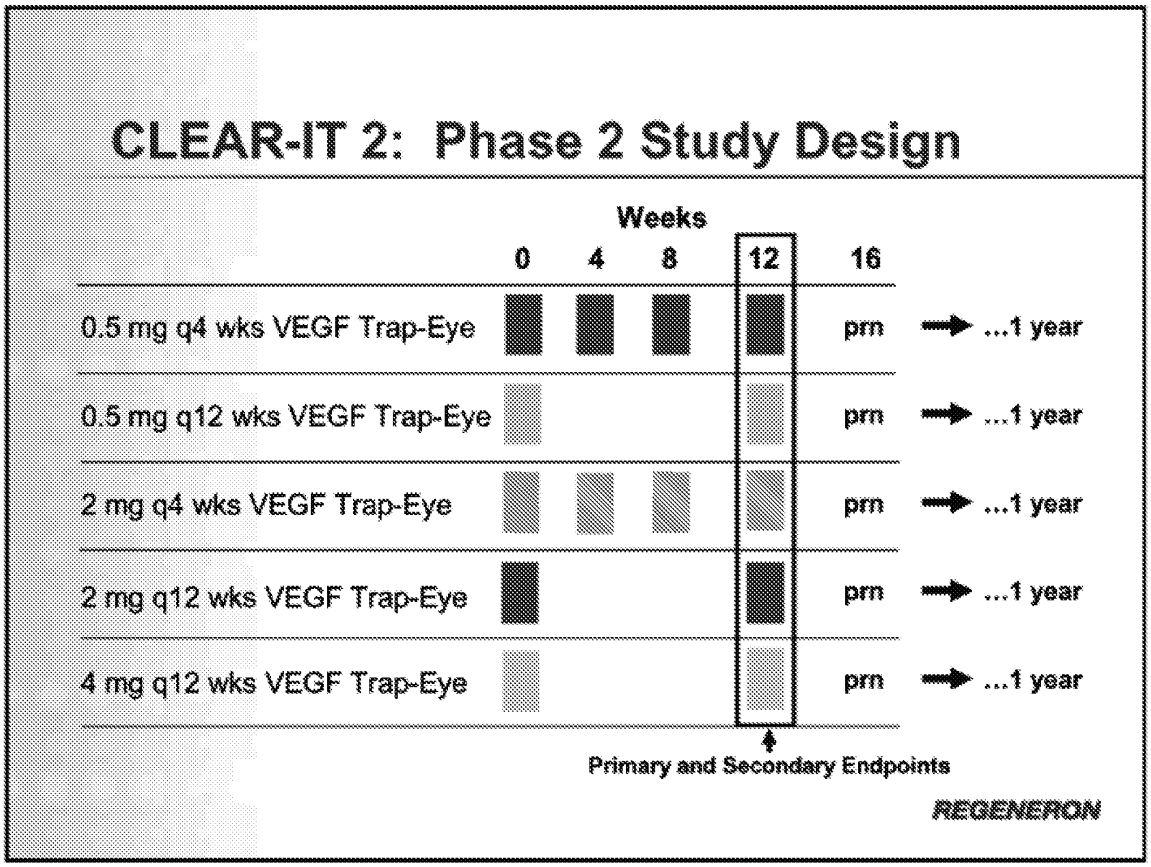
REGENERON

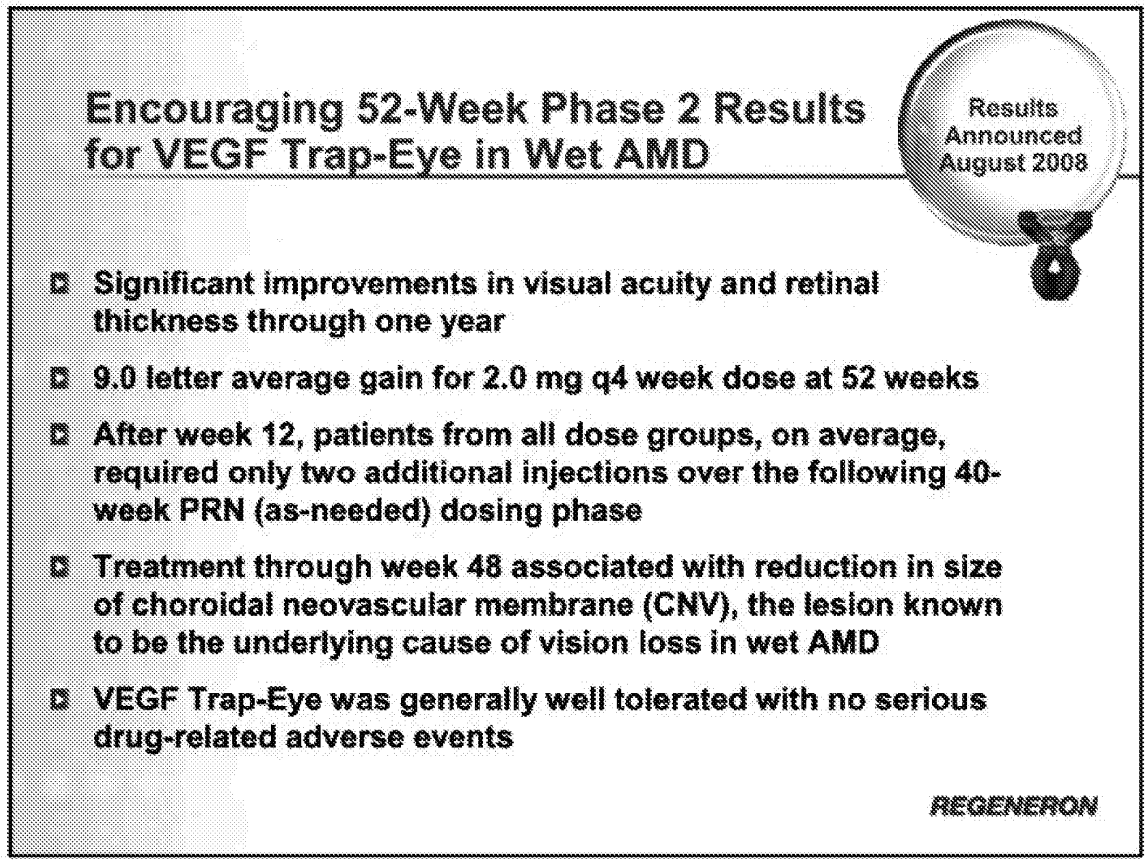
Ranibizumab Findings in Wet AMD

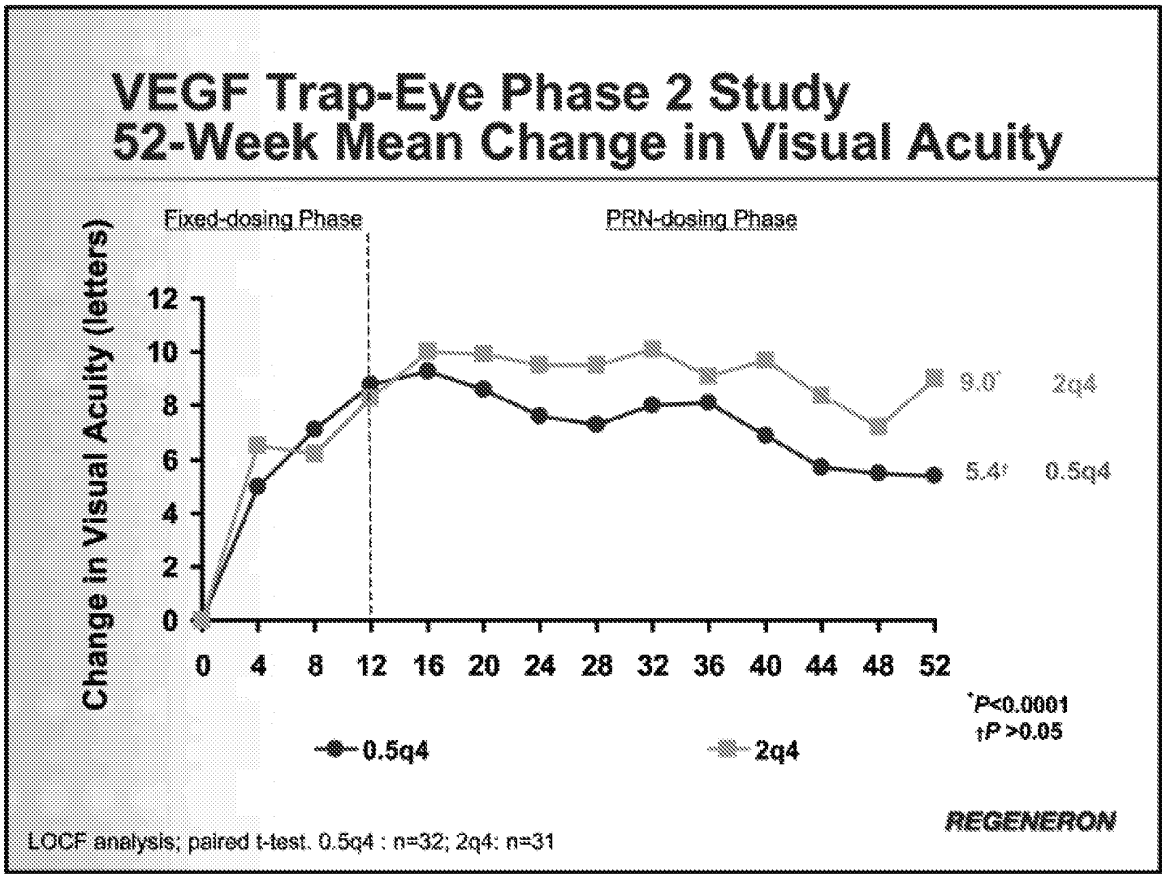
Monthly Dosing	12-Month Change in Visual Acuity vs. Baseline (Letters)
ANCHOR Phase 3	
Monthly dosing	
0.3 mg	+8.5
0.5 mg	+11.3
MARINA Phase 3	
Monthly dosing	
0.3 mg	+6.5
0.5 mg	+7.2

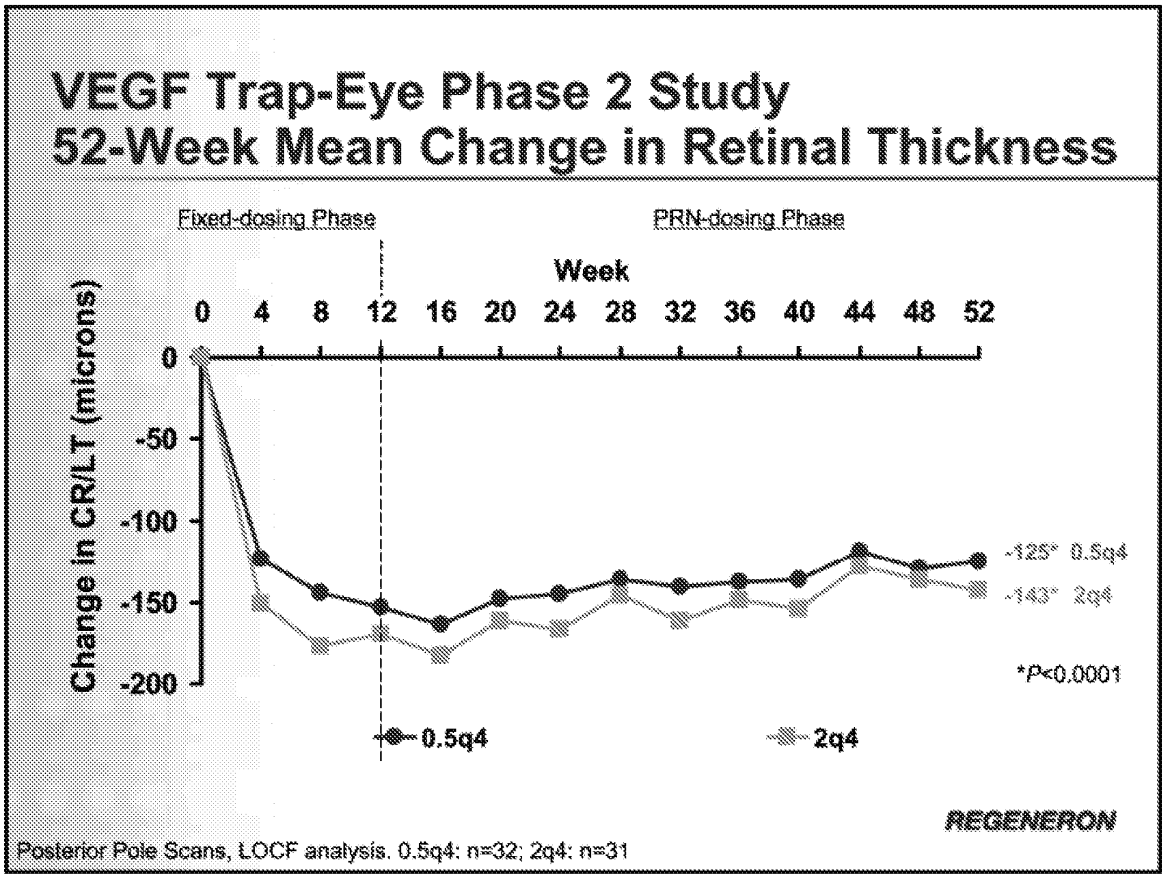
Infrequent Dosing	12-Month Change in Visual Acuity vs. Baseline (Letters)
SAILOR Phase 3b	
3 monthly doses followed by PRN dosing	
0.3 mg	+0.5
0.5 mg	+2.3
PIER Phase 3b	
3 monthly doses followed by quarterly dosing	
0.3 mg	-1.6
0.5 mg	-0.2

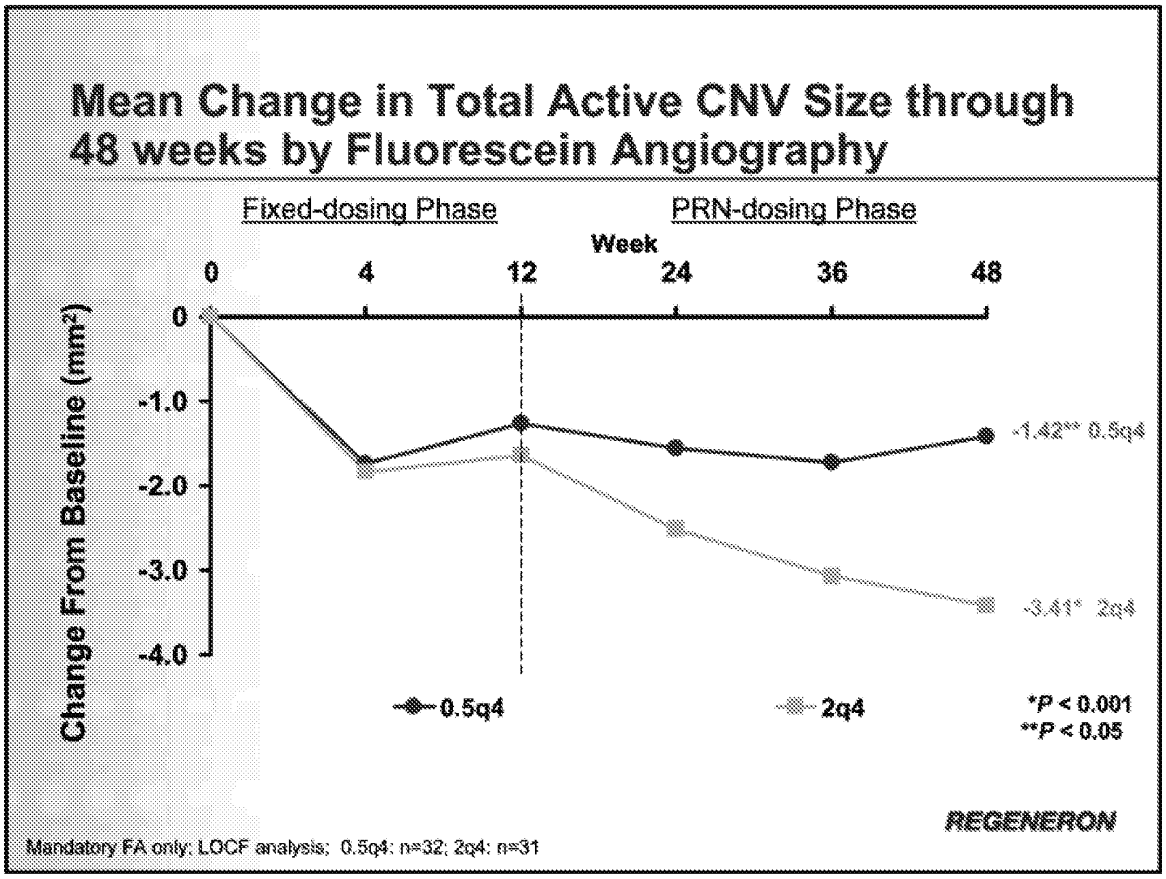
REGENERON


CLEAR-IT 2: Phase 2 Study Design
Weeks
0
4
8
12
16
0.5 mg q4 wks VEGF Trap-Eye
prn
...1 year
0.5 mg q12 wks VEGF Trap-Eye
prn
...1 year
2 mg q4 wks VEGF Trap-Eye
prn
...1 year
2 mg q12 wks VEGF Trap-Eye
prn
...1 year
4 mg q12 wks VEGF Trap-Eye
prn
...1 year
Primary and Secondary Endpoints
REGENERON

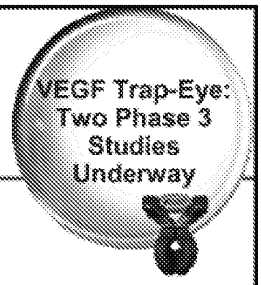

Encouraging 52-Week Phase 2 Results for VEGF Trap-Eye in Wet AMD
Results Announced August 2008
Significant improvements in visual acuity and retinal thickness through one year
9.0 letter average gain for 2.0 mg q4 week dose at 52 weeks
After week 12, patients from all dose groups, on average, required only two additional injections over the following 40-week PRN (as-needed) dosing phase
Treatment through week 48 associated with reduction in size of choroidal neovascular membrane (CNV), the lesion known to be the underlying cause of vision loss in wet AMD
VEGF Trap-Eye was generally well tolerated with no serious drug-related adverse events
REGENERON


VEGF Trap-Eye Phase 2 Study
52-Week Mean Change in Visual Acuity
Fixed-dosing Phase
PRN-dosing Phase
Change in Visual Acuity (letters)
12
10
8
6
4
2
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
9.0* 2q4
5.4† 0.5q4
*P<0.0001
†P >0.05
0.5q4
2q4
REGENERON
LOCF analysis; paired t-test. 0.5q4 : n=32; 2q4: n=31


VEGF Trap-Eye Phase 2 Study
52-Week Mean Change in Retinal Thickness
Fixed-dosing Phase
PRN-dosing Phase
Week
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Change in CR/LT (microns)
0
-50
-100
-150
-200
-125* 0.5q4
-143* 2q4
*P<0.0001
0.5q4
2q4
REGENERON
Posterior Pole Scans, LOCF analysis. 0.5q4: n=32; 2q4: n=31


Mean Change in Total Active CNV Size through 48 weeks by Fluorescein Angiography
Fixed-dosing Phase
PRN-dosing Phase
Week
0
4
12
24
36
48
Change From Baseline (mm²)
0
-1.0
-2.0
-3.0
-4.0
-1.42** 0.5q4
-3.41* 2q4
0.5q4
2q4
*P < 0.001
**P < 0.05
REGENERON
Mandatory FA only; LOCF analysis; 0.5q4: n=32; 2q4: n=31

VEGF Trap-Eye
Phase 3 Program in Wet AMD



- **VIEW 1 enrolling 1200 patients in U.S. and Canada**
- **VIEW 2 enrolling 1200 patients in rest of world**
- **4 arms in both trials**
  - **VEGF Trap-Eye**
    - 0.5 mg q4 weeks
    - 2.0 mg q4 weeks
    - 2.0 mg q8 weeks (after 3 monthly doses)
  - **ranibizumab**
    - 0.5 mg q4 weeks
- **Fixed dosing for 52 weeks (primary endpoint measurement) followed by PRN dosing for 44 weeks**
- **Initial data for primary endpoint expected 2010**

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VEGF Trap-Eye
Phase 2 Program in DME

- Double-masked, randomized, controlled study
- 5 arms: 4 VEGF Trap-Eye regimens vs. laser treatment
- Enrolling approximately 200 patients in U.S., Canada, EU and Australia
- 52 weeks of treatment with 6 month additional safety follow-up
- Primary efficacy endpoint: Change in best corrected visual acuity (BCVA) from baseline to week 24

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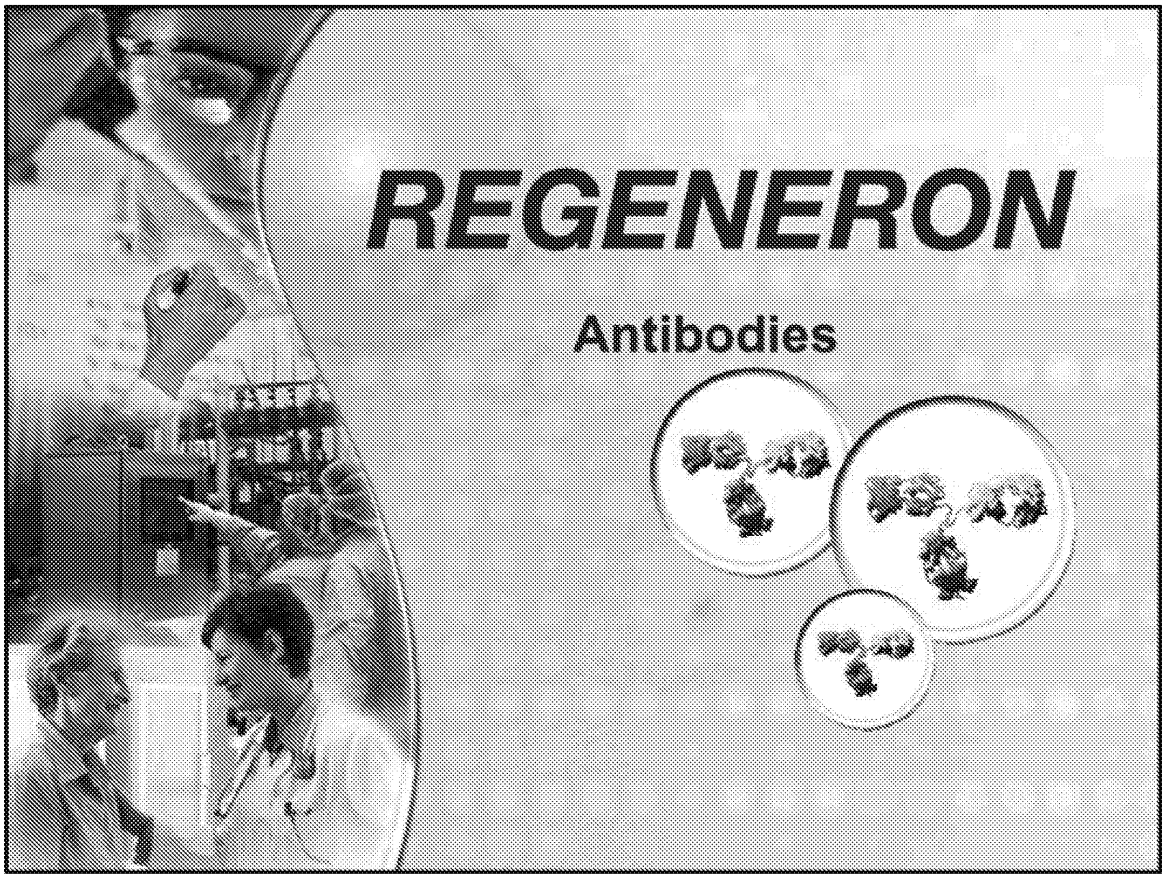
Samsung Bioepis Exhibit 1017, pg. 5015


REGENERON
Antibodies

VelociSuite of Technologies: Target Identification and Validation

VelociGene®

VelociMouse®

High-throughput generation of almost any desired genetic alteration in mouse embryonic stem cells

High-throughput generation of mouse models directly from embryonic stem cells containing genetically altered target genes

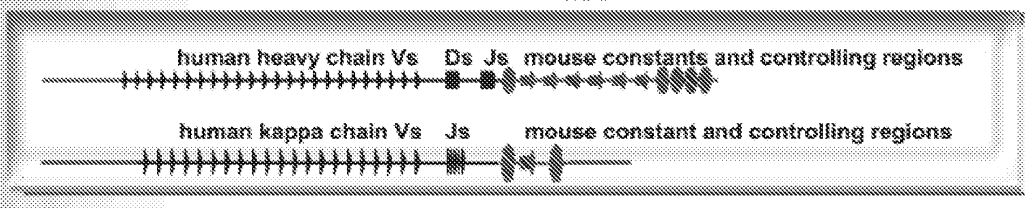
Together, used to identify and validate drug targets:

- Rapidly replaces gene with reporter to see where gene is active
- Shows the result of deleting or adding extra copies of genes
- Allows direct testing in mammalian models of whether the gene product is an important target in a disease setting and for therapeutic intervention
- Selected to play major role in NIH Knockout Mouse Project

REGENERON

VelociSuite of Technologies: Human Antibody Generation and Manufacturing

VelocImmune®	*VelociMab™*
Rapid generation of high-quality, fully human antibodies	**High-throughput antibody screening and selection and high-expression, manufacturing cell line development**
▪ **Genetically humanized over 6 megabases of mouse immune genome**	▪ **Antibodies with most desirable therapeutic characteristics are identified**
▪ ***VelocImmune* mice mount a robust immune response and generate antibodies as efficiently as normal mice**	▪ **Antibodies cloned into high-expression manufacturing cell lines, suitable for clinical and commercial use**



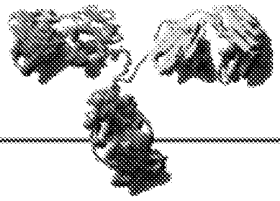
REGENERON

Sanofi-Aventis Antibody Collaboration

- Global collaboration to discover, develop, and commercialize therapeutic human antibodies
- Sanofi-aventis funds $475 million of discovery research over five years through 2012
- Sanofi-aventis funds 100% of development costs for collaboration antibodies
- Goal is to bring average of 2 to 3 new antibodies into clinical development each year
- One antibody in Phase 1 plus two more INDs filed

REGENERON

REGN88: IL-6R Antibody



- Phase 1 trial initiated in rheumatoid arthritis
- IL-6 plays important role in regulation of inflammatory and immune responses
- Clinical proof-of-concept for IL-6R antibody in rheumatoid arthritis demonstrated by Roche's tocilizumab
  - FDA approval pending
- Regeneron antibody is highly potent, fully human IL-6R blocking antibody with potential advantages (including subcutaneous delivery) over competitors

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REGN421: Dll4 Antibody

- Delta-like ligand 4 inhibition being studied for its role in anti-angiogenesis
- IND filed December 2008
- Phase 1 single-agent, dose-ranging study to begin in patients with advanced malignancies

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REGN475: Selective Anti-NGF Antibody

- Clinical proof-of-concept for nerve growth factor (NGF) inhibition in treatment of pain demonstrated by Pfizer's tanezumab, currently in Phase 3 trials for osteoarthritis
- Challenge: Obtain an antibody that binds NGF selectively without cross-reacting, even at high concentrations, with other members of neurotrophin family (e.g., NT-3, NT-4)
- Solution: *VelocImmune*® technology yields highly selective anti-NGF antibody
- IND for REGN475 filed in December 2008
- Phase 1 dose-ranging trial to begin in healthy volunteers

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REGENERON
Growth

Expanding Research and Development, Clinical, and Manufacturing

- Regeneron's headquarters and research laboratories located in Tarrytown, NY
- 230,000 SF of world-class lab and office space under construction
- Expected occupancy in mid-2009

- Biologics manufacturing capacity being expanded from 22,000 to 50,000 liters at our Rensselaer, NY facility
- Additional 272,000 SF building purchased in late 2007 suitable for manufacturing and warehouse space

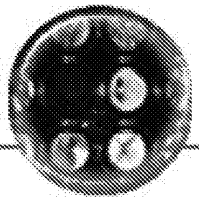
REGENERON

Strong Financial Position

- Year-end 2008 cash and securities: ~$528MM
- No debt: In 2008, retired $200MM of convertible notes

REGENERON

Monetizing Technology



- *VelociGene*® **Knock-Out and Transgenic Models**
  - sanofi-aventis (August 2008)
  - Terms: $4.3MM/year for 5 years
- *VelocImmune*® **Technology Licenses**
  - **Corporate**
    - Astellas Pharma (March 2007) and AstraZeneca/Cambridge Antibody Technology (February 2007)
    - Terms:
      - $20MM/year each for up to 6 years (minimum 4 years)
      - Mid-single-digit royalty on antibody sales
  - **Academic**
    - Columbia University (September 2008)
    - Terms: Regeneron has exclusive option to license antibodies for development and commercialization

REGENERON

Collaboration Agreements

	Oncology	Eye Disease	Antibodies	Inflammation
	sanofi-aventis	Bayer HealthCare	sanofi-aventis	–
Upfront/milestone payments	$130MM	$95MM	$85MM	–
Development costs paid by partner *	100%	~50%	100%**	–
Profit split – Regeneron share				
US	50%	100%	50%	100%
Japan	~35% royalty	50%	35-45%	100%
ROW	50%	50%	35-45%	100%
Milestones remaining				
Regulatory	$400MM	$90MM	–	–
Sales	–	$135MM	$250MM	–

* 50% repayment from profits ** plus $475MM of research funding over 5 years

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Mylan Exhibit 1017
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Samsung Bioepis Exhibit 1017, pg. 5028

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 5/1/2009

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 1, 2009 (April 30, 2009)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	000-19034	13-3444607
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On April 30, 2009, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 2009. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated April 30, 2009.

SIGNATURES

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 hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: May 1, 2009

By: /s/ Stuart Kolinski
Name: Stuart Kolinski
Title: Senior Vice President and General Counsel

Exhibit Index

Number	Description
99.1	Press Release dated April 30, 2009

For Immediate Release

Press Release

Regeneron Reports First Quarter 2009 Financial and Operating Results

Tarrytown, New York (April 30, 2009) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the first quarter 2009. The Company reported a net loss of $17.5 million, or $0.22 per share (basic and diluted), for the first quarter of 2009 compared with a net loss of $11.6 million, or $0.15 per share (basic and diluted), for the first quarter of 2008.

At March 31, 2009, cash, restricted cash, and marketable securities totaled $496.0 million compared with $527.5 million at December 31, 2008.

Current Business Highlights

ARCALYST® (rilonacept) – Inflammatory Diseases

The Company shipped $4.3 million of ARCALYST®(rilonacept) Injection for Subcutaneous Use to its U.S. distributors during the first quarter of 2009, compared to $0.8 million during the first quarter of 2008. Shipments of ARCALYST began in the United States in March 2008 following marketing approval of ARCALYST from the U.S. Food and Drug Administration (FDA) in February 2008 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. ARCALYST, an interleukin-1 (IL-1) blocker, is the only therapy approved in the United States for patients with CAPS. The Company currently projects shipments of ARCALYST to its distributors to total approximately $15-20 million in 2009.

During the first quarter of 2009, the Company initiated a Phase 3 clinical development program with ARCALYST for the treatment of gout. The program includes four clinical trials, three of which are currently enrolling patients: Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) will evaluate ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) 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 program also includes a separate placebo-controlled safety study (RE-SURGE). The Company expects to report initial data from the Phase 3 program in 2010. Regeneron owns worldwide rights to ARCALYST.

Aflibercept (VEGF Trap) – Oncology

At the end of the first quarter of 2009, approximately one-half of the planned number of patients were enrolled in four Phase 3 trials that are evaluating combinations of aflibercept, an investigational anti-angiogenesis agent, with standard chemotherapy regimens for the treatment of cancer. One trial (called 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 (VANILLA) is evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine. A third trial (VITAL) is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel. The fourth trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. All four trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. Initial data from the Phase 3 program are expected in 2010. In addition, a Phase 2 study (AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin began recruiting patients in January 2009.

A Phase 2 single-agent study of aflibercept in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA) is now fully enrolled, and initial data from this trial are expected by mid-2009. Aflibercept is being developed worldwide by Regeneron and its collaborator, sanofi-aventis.

VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications that is being developed by Regeneron and its collaborator, Bayer HealthCare, for the treatment of the neovascular form of Age-related Macular Degeneration (wet AMD), Diabetic Macular Edema (DME), Central Retinal Vein Occlusion (CRVO), and other eye diseases and disorders.

In a separate news release today, Regeneron and Bayer HealthCare announced plans to initiate a Phase 3 program later this year of VEGF Trap-Eye in the treatment of CRVO. Dosing of the first patient in the Phase 3 program will entitle Regeneron to receive a $20.0 million milestone payment.

The Phase 3 program (consisting of the VIEW 1 and VIEW 2 studies) that is evaluating VEGF Trap-Eye in patients with wet AMD continued to enroll patients during the first quarter of 2009. The companies expect to complete enrollment in both trials in 2009 and report initial data in late 2010.

Results of the extension stage of the Phase 2 study in wet AMD (the CLEAR-IT 2 study) will be presented on May 4 at the 2009 Association for Research in Vision and Ophthalmology (ARVO) meeting in Fort Lauderdale, Florida. In late 2008, the companies reported CLEAR-IT 2 study results, which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year.

In the original Phase 2 study, 157 patients were initially treated for 3 months with VEGF Trap-Eye: two groups received monthly doses of 0.5 or 2.0 mg (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg (at baseline and week 12). Following the initial 3-month fixed-dosing phase, patients continued to receive VEGF Trap-Eye at the same dose on a PRN dosing schedule through one year, based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria.

The data to be presented at ARVO will report on 117 patients who elected to enter the extension stage of the study after receiving VEGF Trap-Eye for one year. These patients were dosed on a 2.0 mg PRN basis. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters ($p<0.0001$ versus baseline) at the 3-month primary endpoint of the original Phase 2 study, 8.4 letters ($p<0.0001$ versus baseline) at one year, and 7.1 letters ($p<0.0001$ versus baseline) at month 6 of the extension stage. Thus, after 18 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 3.5 injections over the 15-month PRN dosing phase that extended from month 3 to month 18. Patients continue to be dosed in the extension stage of the Phase 2 study.

Among all the patients in the Phase 2 wet AMD study, VEGF Trap-Eye was generally well tolerated and there were no drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye and two arterial thrombotic events; these were deemed not to be drug-related. Three deaths were reported—one patient with pancreatic cancer, one patient with squamous cell carcinoma of the lung, and one patient with pulmonary hypertension (a pre-existing condition), The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

In the Phase 2 DME study, additional clinical sites were opened during the first quarter of 2009. The study (called DA VINCI) is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study began in December 2008 and is expected to complete enrollment of approximately 200 patients in the U.S., Canada, European Union, and Australia by the end of 2009.

Bayer HealthCare has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

Monoclonal Antibodies

Phase 1 clinical studies have begun with the first three human monoclonal antibodies generated by Regeneron using its *VelocImmune®* technology. REGN88 is an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis. REGN475, an antibody to Nerve Growth Factor (NGF) that binds NGF selectively without cross-reacting with other members of the neurotrophin family, is being developed for the treatment of pain. In addition, a Phase 1 trial is in the process of being initiated to evaluate REGN421, an antibody to Delta-like ligand-4 (Dll4), in patients with advanced malignancies. These antibodies are being developed within the Company's human antibody collaboration with sanofi-aventis. Over the course of the next several years, the Company and sanofi-aventis plan to advance an average of two to three new fully human monoclonal antibodies into clinical development each year.

As part of its Academic *VelocImmune* Investigators' Program (Academic VIP), during the first quarter of 2009 Regeneron entered into an agreement with The University of Texas Southwestern Medical Center that will provide researchers at the Dallas-based medical center with access to Regeneron's *VelocImmune* technology to discover fully human monoclonal antibodies. Regeneron retains the right to develop and commercialize any antibodies discovered under the program.

Financial Results

Revenues

Total revenues increased to $75.0 million in the first quarter of 2009 from $56.4 million in the same period of 2008. The Company's revenue was comprised of contract research and development revenue, technology licensing revenue, and net product sales.

Contract Research and Development Revenue

Contract research and development revenue relates primarily to the Company's aflibercept and antibody collaborations with sanofi-aventis and the Company's VEGF Trap-Eye collaboration with Bayer HealthCare. Contract research and development revenue for the three months ended March 31, 2009 and 2008 consisted of the following:

	Three months ended March 31,	
(In millions)	2009	2008
Contract research & development revenue		
Sanofi-aventis	$ 49.6	$ 35.7
Bayer HealthCare	10.0	9.0
Other	1.5	1.7
Total contract research & development revenue	$ 61.1	$ 46.4

For the three months ended March 31, 2009 and 2008, contract research and development revenue from sanofi-aventis consisted of the following:

	Three months ended March 31,	
(In millions)	2009	2008
Aflibercept:		
Regeneron expense reimbursement	$ 5.4	$ 11.7
Recognition of deferred revenue related to up-front payments	2.5	2.1
Total aflibercept	7.9	13.8
Antibody:		
Regeneron expense reimbursement	38.4	19.3
Recognition of deferred revenue related to up-front payment	2.6	2.6
Other	0.7	
Total antibody	41.7	21.9
Total sanofi-aventis contract research & development revenue	$ 49.6	$ 35.7

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in the first quarter of 2009, compared to the same period in 2008, primarily due to lower costs associated with manufacturing clinical drug supplies.

Sanofi-aventis' reimbursement of Regeneron's expenses under the antibody collaboration increased in the first quarter of 2009, compared to the same period in 2008, due to an increase in research activities conducted under the collaboration's discovery agreement and increases in development activities for REGN88, REGN421, and REGN475 under the collaboration's license agreement.

For the three months ended March 31, 2009 and 2008, contract research and development revenue from Bayer HealthCare consisted of the following:

	Three months ended March 31,	
(In millions)	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 7.5	$ 5.7
Recognition of deferred revenue related to up-front and milestone payments	2.5	3.3
Total Bayer HealthCare contract research & development revenue	$ 10.0	$ 9.0

In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration with Bayer HealthCare, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. The Company incurred higher VEGF Trap-Eye development expenses under the collaboration for the three months ended March 31, 2009, compared to the same period in 2008, primarily in connection with the collaboration's clinical development programs in wet AMD and DME.

Technology Licensing Revenue

Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that allow those companies to utilize *VelocImmune®* technology in their internal research programs to discover human monoclonal antibodies. Each company is required to make six $20.0 million annual, non-refundable payments, subject to the ability to terminate their agreements after making a total of four such payments. To date, the Company has received $60.0 million in payments from AstraZeneca and $40.0 million in payments from Astellas under these agreements. Upon receipt, these payments are deferred and recognized as revenue ratably over the ensuing year of each agreement. Regeneron will also receive a mid-single-digit royalty on sales of any antibodies discovered utilizing *VelocImmune*.

Net Product Sales
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. For the three months ended March 31, 2009, the Company recognized as revenue $3.9 million of ARCALYST® (rilonacept) net product sales for which the right of return no longer exists and rebates can be reasonably estimated. At March 31, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled $4.2 million and $0.8 million, respectively.

Expenses
Total operating expenses for the first quarter of 2009 were $94.2 million, 30 percent higher than the same period in 2008. Average headcount increased to 938 for the first quarter of 2009 compared to 714 for the same period in 2008, due primarily to the Company's expanding research and development activities principally in connection with the sanofi-aventis antibody collaboration. Operating expenses included non-cash compensation expense related to employee stock option and restricted stock awards of $7.7 million and $8.3 million, in the first quarters of 2009 and 2008, respectively.

Research and development (R&D) expenses increased to $82.1 million in the first quarter of 2009 from $61.3 million in the comparable quarter of 2008. In the first quarter of 2009, the Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for ARCALYST, VEGF Trap-Eye, and REGN88, research and preclinical development costs associated with the antibody programs, and facility-related costs to support expanded R&D activities.

Selling, general, and administrative (SG&A) expenses increased to $11.7 million in the first quarter of 2009 from $11.0 million in the comparable quarter of 2008. In the first quarter of 2009, the Company incurred higher selling expenses related to ARCALYST® (rilonacept), higher compensation expense associated with expanding the Company's SG&A headcount, and higher SG&A facility-related costs.

Other Income and Expense
Investment income decreased to $1.8 million in the first quarter of 2009 from $7.3 million in the comparable quarter of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in the first quarter of 2009 compared to the same quarter in 2008. Interest expense in the first quarter of 2008 was attributable to the Company's 5.5% Convertible Senior Subordinated Notes; no Notes were outstanding in 2009.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, inflammatory diseases, and pain, and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2008. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	March 31, 2009	December 31, 2008
ASSETS		
Cash, restricted cash, and marketable securities	$ 495,992	$ 527,461
Receivables	48,209	35,212
Property, plant, and equipment, net	109,840	87,853
Other assets	27,380	19,512
Total assets	$ 681,421	$ 670,038
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 44,832	$ 36,168
Deferred revenue	213,119	209,925
Other liabilities	13,150	5,093
Stockholders' equity	410,320	418,852
Total liabilities and stockholders' equity	$ 681,421	$ 670,038

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended March 31,	
	2009	2008
Revenues		
Contract research and development	$ 61,090	$ 46,383
Technology licensing	10,000	10,000
Net product sales	3,891	
	74,981	56,383
Expenses		
Research and development	82,146	61,270
Selling, general, and administrative	11,674	11,024
Cost of goods sold	392	
	94,212	72,294
Loss from operations	(19,231)	(15,911)
Other income (expense)		
Investment income	1,750	7,304
Interest expense		(3,011)
	1,750	4,293
Net loss	$ (17,481)	$ (11,618)
Net loss per share amounts, basic and diluted	$ (0.22)	$ (0.15)
Weighted average shares outstanding, basic and diluted	79,498	78,493

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 11/4/2009

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 4, 2009 (November 3, 2009)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	000-19034	13-3444607
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2009, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended September 30, 2009. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated November 3, 2009.

SIGNATURES

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 hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: November 4, 2009

By: /s/ Stuart Kolinski
Name: Stuart Kolinski
Title: Senior Vice President and General Counsel

Exhibit Index

Number	Description
99.1	Press Release dated November 3, 2009.

REGENERON

Exhibit 99.1

For Immediate Release

Press Release

Regeneron Reports Third Quarter 2009 Financial and Operating Results

Tarrytown, New York (November 3, 2009) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial and operating results for the third quarter of 2009. The Company reported a net loss of $1.0 million, or $0.01 per share (basic and diluted), for the third quarter of 2009 compared with a net loss of $19.1 million, or $0.24 per share (basic and diluted), for the third quarter of 2008. The Company reported a net loss of $31.3 million, or $0.39 per share (basic and diluted), for the nine months ended September 30, 2009 compared with a net loss of $49.6 million, or $0.63 per share (basic and diluted), for the same period in 2008. During the third quarter of 2009, the Company recognized as revenue a $20.0 million milestone payment from Bayer HealthCare, as described below.

At September 30, 2009, cash, restricted cash, and marketable securities totaled $438.6 million compared with $527.5 million at December 31, 2008.

Current Business Highlights

ARCALYST® (rilonacept) – Inflammatory Diseases

The Company shipped $5.3 million of ARCALYST® (rilonacept) Injection for Subcutaneous Use to its U.S. distributors during the third quarter of 2009, compared to $4.3 million in the same quarter of 2008. Shipments during the first nine months of 2009 were $15.0 million compared to $6.7 million for the same period of 2008. ARCALYST, an interleukin-1 (IL-1) blocker, was approved in the United States in February 2008 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. The Company currently projects shipments of ARCALYST to its U.S. distributors to total approximately $20 million in 2009. In October 2009, rilonacept was approved under exceptional circumstances by the European Medicines Agency (EMEA) for the treatment of CAPS with severe symptoms in adults and children aged 12 years and older.

ARCALYST is in a Phase 3 clinical development program for the treatment of gout. The program includes four clinical trials, all of which are currently enrolling patients. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) is evaluating treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a placebo-controlled safety study (RE-SURGE). The Company expects to report initial data from the Phase 3 program in the first half of 2010. Regeneron owns worldwide rights to ARCALYST (rilonacept).

Aflibercept (VEGF Trap) – Oncology

Aflibercept, an anti-angiogenic protein product candidate designed to bind all forms of vascular endothelial growth factor A (VEGF-A), is being developed worldwide by Regeneron and its collaborator, sanofi-aventis. At the end of the third quarter of 2009, more than 80 percent of the planned number of patients were enrolled in each of three Phase 3 trials that are evaluating combinations of aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial (called 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 metastatic non-small cell lung cancer in combination with docetaxel. The third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. All three trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. Analyses of the data from these studies will be conducted when a prespecified number of events have occurred in each trial. Based on current enrollment and event rates, an interim analysis of the Phase 3 study in colorectal cancer is expected to be conducted by an independent data monitoring committee (IDMC) in the second half of 2010. Complete results from this study in colorectal cancer and from the study in non-small cell lung cancer are anticipated in the first half of 2011. Based on the current enrollment and number of events, an interim analysis of the prostate study is expected to be conducted by an IDMC in mid-2011, with complete results anticipated in 2012. In addition, a Phase 2 study (AFFIRM) is being conducted of aflibercept in 1st line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin.

In September 2009, as previously reported, a fourth Phase 3 trial (VANILLA) that was evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC. As part of a planned interim efficacy analysis, the Committee determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine in this study. The types and frequencies of adverse events reported on the combination arm with aflibercept were generally as anticipated.

VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye, a specially purified and formulated form of VEGF Trap for use in intraocular treatment of retinal disease, is being developed by Regeneron and its collaborator, Bayer HealthCare. Two Phase 3 studies (VIEW 1 and VIEW 2) evaluating VEGF Trap-Eye in patients with the neovascular form of Age-related Macular Degeneration (wet AMD) are now fully enrolled, and we expect initial data from this program to be reported in late 2010. A Phase 2 study (called DA VINCI) of VEGF Trap-Eye for the treatment of the Diabetic Macular Edema (DME) is also fully enrolled, with data expected during the first half of 2010. Additionally, two Phase 3 studies in Central Retinal Vein Occlusion (CRVO) are enrolling patients; data from the first of these studies are anticipated to be available in the first half of 2011.

During October 2009, 24-month results of the extension stage of the Phase 2 study of VEGF Trap-Eye in wet AMD (CLEAR-IT 2) were presented at the 2009 American Academy of Ophthalmology meeting. After receiving VEGF Trap-Eye for one year, the 117 patients who elected to enter the extension stage were dosed on a 2.0 mg PRN basis, irrespective of the dose at which they were treated earlier in the study. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters (p<0.0001 versus baseline) at the three-month primary endpoint of the original Phase 2 study, 8.4 letters (p<0.0001 versus baseline) at one year, and 6.1 letters (p<0.0001 versus baseline) at month 12 of the extension study. Thus, after 24 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 4.6 injections over the 21-month PRN dosing phase that extended from month three to month 24. The most common adverse events were those typically associated with intravitreal injection.

Bayer HealthCare has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

Monoclonal Antibodies

During the third quarter of 2009, REGN475, an antibody to Nerve Growth Factor (NGF), a novel target for pain, began a dose ranging study in osteoarthritis of the knee. Trial results are expected during the first half of 2010. A Phase 1 study of REGN475 in healthy volunteers is also continuing, and Phase 1 studies are in progress with REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis, and REGN421, an antibody to Delta-like ligand-4 (Dll4) that is being studied in patients with advanced malignancies. REGN475, REGN88, and REGN421 are fully human monoclonal antibodies generated by Regeneron using the *VelocImmune®* technology and developed within the Company's human antibody collaboration with sanofi-aventis. Regeneron and sanofi-aventis expect to enter two more human monoclonal antibodies into clinical development this year and to advance an average of two to three into clinical development each year thereafter over the next several years.

Financial Results

Revenues
Total revenues increased to $117.5 million in the third quarter of 2009 from $65.6 million in the same quarter of 2008 and increased to $282.5 million for the first nine months of 2009 from $182.6 million for the same period of 2008. The Company's revenue was comprised of contract research and development revenue, a 2009 research progress payment, technology licensing revenue, and net product sales.

Contract Research and Development Revenue
Contract research and development revenue relates primarily to the Company's aflibercept and antibody collaborations with sanofi-aventis and the Company's VEGF Trap-Eye collaboration with Bayer HealthCare. Contract research and development revenue for the three and nine months ended September 30, 2009 and 2008 consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	2009	2008	2009	2008
Contract research & development revenue:				
Sanofi-aventis	$ 68.5	$ 42.0	$ 178.9	$ 116.3
Bayer HealthCare	12.2	9.0	34.9	28.2
Other	1.8	1.9	5.3	5.4
Total contract research & development revenue	$ 82.5	$ 52.9	$ 219.1	$ 149.9

For the three and nine months ended September 30, 2009 and 2008, contract research and development revenue from sanofi-aventis consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	2009	2008	2009	2008
Aflibercept:				
Regeneron expense reimbursement	$ 7.0	$ 7.3	$ 21.6	$ 29.3
Recognition of deferred revenue related to up-front payments	2.5	2.1	7.4	6.2
Total aflibercept	9.5	9.4	29.0	35.5
Antibody:				
Regeneron expense reimbursement	55.7	29.5	139.8	72.4
Recognition of deferred revenue related to up-front payment	2.6	2.6	7.9	7.9
Recognition of revenue related to *VelociGene*® agreement	0.7	0.5	2.2	0.5
Total antibody	59.0	32.6	149.9	80.8
Total sanofi-aventis contract research & development revenue	$ 68.5	$ 42.0	$ 178.9	$ 116.3

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased for the three and nine months ended September 30, 2009, compared to the same periods in 2008, primarily due to lower Company costs associated with internal research activities and, for the nine months ended September 30, 2009, lower costs related to manufacturing clinical drug supplies. Sanofi-aventis also incurs aflibercept development expenses directly, including costs related to the Phase 3 clinical trials sanofi-aventis is overseeing in the oncology program.

Sanofi-aventis' reimbursement of Regeneron's expenses under the antibody collaboration increased for the three and nine months ended September 30, 2009, compared to the same periods in 2008, due to an increase in research activities conducted under the collaboration's discovery agreement and increases in development activities for antibody candidates, including REGN88, REGN421, and REGN475, under the collaboration's license agreement.

For the three and nine months ended September 30, 2009 and 2008, contract research and development revenue from Bayer HealthCare consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	2009	2008	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 9.7	$ 5.7	$ 27.5	$ 18.3
Recognition of deferred revenue related to up-front and non-substantive milestone payments	2.5	3.3	7.4	9.9
Total Bayer HealthCare contract research & development revenue	$ 12.2	$ 9.0	$ 34.9	$ 28.2

In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration with Bayer HealthCare, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. The Company incurred higher VEGF Trap-Eye development expenses under the collaboration for the three and nine months ended September 30, 2009, compared to the same period in 2008, primarily in connection with the collaboration's clinical development programs in wet AMD, DME, and CRVO.

Research Progress Payment
In July 2009, the Company received a $20.0 million substantive milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO. The payment was recognized in revenues as a research progress payment for the three and nine months ended September 30, 2009.

Technology Licensing Revenue
Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that allow those companies to utilize *VelocImmune®* technology in their internal research programs to discover human monoclonal antibodies. Each company is required to make six $20.0 million annual, non-refundable payments, subject to the ability to terminate their agreements after making a total of four such payments. To date, the Company has received $60.0 million in payments from each of AstraZeneca and Astellas under these agreements. Upon receipt, these payments are deferred and recognized as revenue ratably over the ensuing year of each agreement. Regeneron will also receive a mid-single-digit royalty on sales of any antibodies discovered utilizing *VelocImmune*.

Net Product Sales
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. For the three and nine months ended September 30, 2009, the Company recognized as revenue $5.0 million and $13.4 million of ARCALYST® (rilonacept) net product sales, respectively, for which the right of return no longer exists and rebates can be reasonably estimated, compared to $2.7 million for three and nine months ended September 30, 2008. At September 30, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled $5.0 million and $3.8 million, respectively.

Expenses
Total operating expenses for the third quarter of 2009 were $118.7 million, 42 percent higher than the same period in 2008, and $317.2 million for the first nine months of 2009, 34 percent higher than the same period in 2008. Average headcount increased to 998 in the third quarter of 2009 from 851 in the same period of 2008 and increased to 967 for the first nine months of 2009 from 778 in the same period of 2008, due primarily to the Company's expanding research and development activities principally in connection with the sanofi-aventis antibody collaboration. Operating expenses included non-cash compensation expense related to employee stock option and restricted stock awards of $7.5 million in the third quarter of 2009 and $22.6 million for the first nine months of 2009, compared with $8.2 million and $24.7 million, respectively, for the same periods of 2008.

Research and development (R&D) expenses increased to $105.4 million in the third quarter of 2009 from $72.1 million in the comparable quarter of 2008, and to $280.0 million in the first nine months of 2009 from $200.3 million in the same period of 2008. In the third quarter and first nine months of 2009, the Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for ARCALYST, VEGF Trap-Eye, and monoclonal antibodies, research and preclinical development costs associated with the antibody programs, and facility-related costs to support expanded R&D activities.

Selling, general, and administrative (SG&A) expenses increased to $12.8 million in the third quarter of 2009 from $11.1 million in the comparable quarter of 2008, and to $35.9 million in the first nine months of 2009 from $35.7 million in the same period of 2008. In the third quarter and for the first nine months of 2009, the Company incurred higher compensation and facility-related expenses due primarily to increases in administrative headcount to support the expanded research and development activities, higher patent-related costs, and higher expenses related to ARCALYST® (rilonacept), partially offset by lower market research costs related to various programs and a decrease in recruitment costs for administrative headcount.

Other Income and Expense

Investment income decreased to $0.9 million in the third quarter of 2009 from $3.7 million in the comparable quarter of 2008 and to $3.9 million in the first nine months of 2009 compared to $15.5 million in the first nine months of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in 2009 compared to 2008.

Interest expense decreased to $0.6 million in the third quarter of 2009 from $1.8 million in the comparable quarter of 2008, and to $0.6 million in the first nine months of 2009 from $7.5 million in the same period of 2008. Interest expense in 2009 was attributable to the imputed interest portion of the Company's payments to its landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York, which commenced in the third quarter of 2009. Interest expense in 2008 was attributable to the Company's 5.5 percent Convertible Senior Subordinated Notes; no Notes were outstanding in 2009. During the first nine months of 2008, the Company repurchased $82.5 million in principal amount of its 5.5 percent Convertible Senior Subordinated Notes. In connection with the repurchased notes, the Company recognized a $0.9 million loss on early extinguishment of debt. The remaining $117.5 million of these notes were repaid in full upon their maturity in October 2008.

Income Tax Expense

In the third quarter of 2008, the Company incurred and paid income tax expense, consisting primarily of alternative minimum tax, of $3.1 million, which resulted from the utilization of certain net operating loss carry-forwards for tax purposes that would otherwise have expired over the next several years.

Revision of Previously Issued Financial Statements

The Company has revised its financial statements at December 31, 2008 and for the three and nine months ended September 30, 2008 in connection with the application of authoritative guidance issued by the Financial Accounting Standards Board (FASB) to the Company's December 2006 lease, as amended, of laboratory and office facilities in Tarrytown, New York. The revisions consisted entirely of non-cash adjustments, primarily to the Company's balance sheet at December 31, 2008, and had no impact to the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs, including the development of its product candidates. The revisions, and a description of the basis for the revisions, are more fully described in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, inflammatory diseases, and pain, and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2008 and Form 10-Q for the quarter ended September 30, 2009. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	September 30, 2009	December 31, 2008 *(Revised)**
ASSETS		
Cash, restricted cash, and marketable securities	$ 438,596	$ 527,461
Receivables	67,766	35,212
Property, plant, and equipment, net	215,169	142,035
Other assets	20,661	19,512
Total assets	$ 742,192	$ 724,220
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 55,291	$ 36,168
Deferred revenue	198,546	209,925
Facility lease obligation	62,571	54,182
Other long-term liabilities	3,341	2,431
Stockholders' equity	422,443	421,514
Total liabilities and stockholders' equity	$ 742,192	$ 724,220

** Revised as described in the paragraph of this press release titled "Revision of Previously Issued Financial Statements."*

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2009	2008	2009	2008
		*(Revised)**		*(Revised)**
Revenues				
Contract research and development	$ 82,482	$ 52,878	$ 219,104	$ 149,914
Research progress payments	20,000		20,000	
Technology licensing	10,000	10,000	30,000	30,000
Net product sales	4,973	2,706	13,364	2,706
	117,455	65,584	282,468	182,620
Expenses				
Research and development	105,434	72,089	279,972	200,335
Selling, general, and administrative	12,840	11,103	35,892	35,652
Cost of goods sold	472	292	1,299	292
	118,746	83,484	317,163	236,279
Loss from operations	(1,291)	(17,900)	(34,695)	(53,659)
Other income (expense)				
Investment income	857	3,674	3,935	15,513
Interest expense	(581)	(1,772)	(581)	(7,457)
Loss on early extinguishment of debt		(7)		(938)
	276	1,895	3,354	7,118
Net loss before income tax expense	(1,015)	(16,005)	(31,341)	(46,541)
Income tax expense		3,079		3,079
Net loss	$ (1,015)	$ (19,084)	$ (31,341)	$ (49,620)
Net loss per share amounts, basic and diluted	$ (0.01)	$ (0.24)	$ (0.39)	$ (0.63)
Weighted average shares outstanding, basic and diluted	79,866	78,937	79,663	78,706

** Revised as described in the paragraph of this press release titled "Revision of Previously Issued Financial Statements."*

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Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 12/20/2010

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 20, 2010 (December 20, 2010)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On December 20, 2010, Regeneron Pharmaceuticals, Inc. ("Regeneron") and Bayer HealthCare issued a press release announcing results for VEGF Trap-Eye (aflibercept ophthalmic solution) in a Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in a Phase 2 Study in Diabetic Macular Edema (DME).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item. As noted during our investor teleconference on December 20, 2010, the attached press release inadvertently omitted certain information, which Regeneron does not consider to be material. To reflect inclusion of such omitted information, the sentence that reads "VEGF Trap-Eye was generally well-tolerated, and there were no ocular or non-ocular drug-related serious adverse events reported in the study" would be replaced with the following "In this study, VEGF Trap-Eye was generally well-tolerated and no patients experienced ocular drug-related serious adverse events. With respect to the number of patients with non-ocular serious adverse events judged by investigators to be drug-related, there were none during the first six months of the study and one in the second six months."

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release Reporting Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME) dated December 20, 2010.

SIGNATURES

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 hereunto duly authorized.

Date: December 20, 2010

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance and Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Exhibit Index

Number	Description
99.1	Press Release Reporting Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME) dated December 20, 2010

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 5062

Samsung Bioepis Exhibit 1017, pg. 5062

REGENERON

Exhibit 99.1

For Immediate Release

Press Release

Regeneron and Bayer Report Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME)

In Phase 3 study in CRVO, 56 percent of VEGF Trap-Eye patients gained at least 15 letters of vision compared to 12 percent in control group; VEGF Trap-Eye patients on average gained 17 letters of vision compared to mean loss of 4 letters in control group

In Phase 2 study in DME, patients in all VEGF Trap-Eye dose groups, including VEGF Trap-Eye dosed every two months, maintained or increased vision gains through 52-weeks

Regeneron to receive $20 million in milestone payments in connection with VEGF Trap-Eye program

Tarrytown, NY, USA, and Berlin, Germany, December 20, 2010 -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Bayer HealthCare today announced positive top-line results for VEGF Trap-Eye (aflibercept ophthalmic solution) in the COPERNICUS study, which is led by Regeneron, the first of two Phase 3 studies in patients with macular edema due to central retinal vein occlusion (CRVO). In this trial, 56.1 percent of patients receiving VEGF Trap-Eye 2 milligrams (mg) monthly gained at least 15 letters of vision from baseline, compared to 12.3 percent of patients receiving sham injections ($p<0.0001$), the primary endpoint of the study. Patients receiving VEGF Trap-Eye 2mg monthly gained, on average, 17.3 letters of vision compared to a mean loss of 4.0 letters with sham injections ($p<0.001$), a secondary endpoint. The second Phase 3 study, GALILEO, is currently ongoing and is led by Bayer HealthCare.

VEGF Trap-Eye was generally well tolerated and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. A total of 114 patients were randomized to receive VEGF Trap-Eye and 73 patients to the control arm. 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 in the 73 (2.7%) patients treated with sham injections.

"In the COPERNICUS trial, patients treated with VEGF Trap-Eye experienced a marked improvement in vision," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "If these results are confirmed by data from the GALILEO study, expected in the second quarter of 2011, VEGF Trap-Eye could provide patients and physicians with a new treatment option for central retinal vein occlusion."

"After reporting positive results from our global Phase 3 program (VIEW 1 and VIEW 2 studies) for the treatment of the neovascular form of age related macular degeneration (wet AMD), we are pleased to also have a positive Phase 3 trial with VEGF Trap-Eye in central retinal vein occlusion, a potential second indication," said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. "We are working diligently with Regeneron to prepare regulatory filings for VEGF Trap-Eye in wet AMD to submit in the first half of 2011."

Detailed results for COPERNICUS will be presented at the Angiogenesis Conference in Miami, Florida in February 2011.

Regeneron will receive a $10 million milestone payment from Bayer HealthCare in connection with the COPERNICUS trial meeting its primary endpoint and received a $10 million milestone payment in December 2010 for the positive VIEW 1 and VIEW 2 trial results in wet AMD.

Phase 2 DME Results
Regeneron and Bayer HealthCare also reported 52 week follow-up results from the Phase 2 DA VINCI study in patients with diabetic macular edema (DME). In this study, the previously reported visual acuity gains achieved with VEGF Trap-Eye treatment over 24 weeks (the primary endpoint of the study) were maintained or numerically improved up to completion of the study at week 52 in all VEGF Trap-Eye study groups, including 2mg dosed every other month. Based on these positive results, Regeneron and Bayer HealthCare are discussing plans to initiate Phase 3 studies.

In this double-masked, prospective, randomized, multi-center Phase 2 trial, entitled **DA VINCI** (**D**ME **A**nd **V**EGF Trap-Eye: **IN**vestigation of **C**linical Impact), 221 patients with clinically significant DME with central macular involvement were randomized and 219 patients were treated with balanced distribution over five groups. The control group received macular laser therapy at baseline, and patients were eligible for repeat laser treatments, but no more frequently than at 16 week intervals. Two groups received monthly doses of 0.5 or 2mg of VEGF Trap-Eye throughout the 12-month dosing period. Two groups received three initial monthly doses of 2mg of VEGF Trap-Eye (at baseline and weeks 4 and 8), followed through week 52 by either every two months dosing or PRN (as-needed) dosing with very strict repeat dosing criteria. Mean gains in visual acuity versus baseline were as follows:

	Laser	0.5mg monthly	2mg monthly	2mg every two months*	2mg PRN*
n	44	44	44	42	45
Mean change in visual acuity at week 24 versus baseline[1] (letters)	2.5	8.6**	11.4**	8.5**	10.3**
Mean change in visual acuity at week 52 versus baseline (letters)	-1.3	11.0**	13.1**	9.7**	12.0**

*Following 3 initial monthly doses
**p<0.01 versus laser
[1] Primary endpoint

No significant differences among the VEGF Trap-Eye arms were observed. Approximately 80 percent of the VEGF Trap-Eye patients and 75 percent of the laser patients remained in the study through 52 weeks.

VEGF Trap-Eye was generally well-tolerated, and there were no ocular or non-ocular drug-related serious adverse events reported in the study. 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 included 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 laser over 12 months.

Detailed results for DA VINCI will be presented at the Angiogenesis Conference in Miami, Florida in February 2011.

About the Phase 3 CRVO Program
Patients in the COPERNICUS (Controlled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) and the identical GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) studies receive six monthly injections of either VEGF Trap-Eye at a dose of 2mg or sham injections. Patients in the COPERNICUS trial were randomized in a 3:2 ratio with 114 patients randomized to receive VEGF Trap-Eye and 73 randomized to the control arm. At the end of the initial six months, all patients randomized to VEGF Trap-Eye are dosed on a PRN (as needed) basis for another six months. In the COPERNICUS trial, patients randomized to sham injections in the first six months are eligible to cross over to VEGF Trap-Eye PRN dosing in the second six months. During the second six months of the studies, all patients are eligible for rescue laser treatment. Visual acuity was measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

About Central Retinal Vein Occlusion (CRVO)
Over 100,000 people in the United States and more than 66,000 people in key European countries are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to a back up of blood and fluid in the retina. This causes retinal injury and loss of vision. The retina can also become "ischemic" (starved for oxygen), resulting in the growth of new, inappropriate blood vessels that can cause further vision loss and more serious complications. Release of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and inappropriate new vessel growth. It is believed that anti-VEGF treatment may help decrease vascular permeability and edema and prevent the inappropriate growth of new blood vessels in the retina in patients with CRVO.

About Diabetic Macular Edema (DME)
DME is the most prevalent cause of moderate vision loss in patients with diabetes. DME is a common complication of Diabetic Retinopathy (DR), a disease affecting the blood vessels of the retina. Clinically significant DME is a leading cause of blindness in younger adults (under 50). Clinically significant DME occurs when fluid leaks into the center of the macula, the light-sensitive part of the retina responsible for sharp, direct vision. Fluid in the macula can cause severe vision loss or blindness.

Approximately 370,000 Americans currently suffer from clinically significant DME, with 95,000 new cases arising each year. According to the American Diabetes Association, more than 18 million Americans currently suffer from diabetes, and many other people are at risk for developing diabetes. With the incidence of diabetes steadily climbing, it is projected that up to 10 percent of all patients with diabetes will develop DME during their lifetime.

About VEGF Trap-Eye
VEGF Trap-Eye is a fully human fusion protein, consisting of soluble VEGF receptors 1 and 2, that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. VEGF Trap-Eye is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Regeneron and Bayer HealthCare are collaborating on the global development of VEGF Trap-Eye for the treatment of the neovascular form of age related macular degeneration (wet AMD), diabetic macular edema (DME), central retinal vein occlusion (CRVO), and other eye diseases and disorders. In November 2010, Regeneron and Bayer HealthCare announced positive top-line results from two parallel Phase 3 studies in patients with wet AMD, VIEW 1 and VIEW 2. In these trials, all regimens of VEGF Trap-Eye, including VEGF Trap-Eye dosed every two months, successfully met the primary endpoint compared to the current standard of care, ranibizumab dosed every month. The primary endpoint was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. A generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies. There were no notable differences in non-ocular adverse events among the study arms. Bayer HealthCare and Regeneron are planning to submit regulatory applications for marketing approval for the treatment of wet AMD in Europe and the U.S. in the first-half of 2011.

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. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration and central retinal vein occlusion), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of more than EUR 15.9 billion (2009), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 53.400 employees and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

Regeneron Forward Looking Statement
This news release includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Astellas, the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2009 and Form 10-Q for the quarter ended September 30, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

Bayer Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 2/18/2011

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 17, 2011 (February 17, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 **Results of Operations and Financial Condition.**

On February 17, 2011, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter and year ended December 31, 2010. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release dated February 17, 2011.

SIGNATURES

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 hereunto duly authorized.

Date: February 17, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance and Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Exhibit Index

Number	Description
99.1	Press Release dated February 17, 2011

Exhibit 99.1

REGENERON

For Immediate Release

Press Release

Regeneron Reports Full Year and Fourth Quarter 2010 Financial and Operating Results

Tarrytown, New York (February 17, 2011) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial results for the full year and fourth quarter of 2010 and provided an update on development programs and upcoming milestones.

"2010 was a very productive year for Regeneron as we reported positive Phase 3 results in four clinical trials: two with VEGF Trap-Eye in wet age-related macular degeneration, called wet AMD, one with VEGF Trap-Eye in central retinal vein occlusion, and one with ARCALYST® for the prevention of gout flares in patients initiating uric-acid lowering therapy," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We expect regulatory applications to be filed in the first half of 2011 for marketing approval in the U.S. and Europe for VEGF Trap-Eye in wet AMD. We also look forward to reporting results from additional Phase 3 trials in central retinal vein occlusion and gout and from two Phase 3 trials with aflibercept in cancer."

"In anticipation of potential product approvals," Dr. Schleifer added, "we are continuing to build our commercialization capabilities. We are also advancing our earlier-stage pipeline which currently includes eight fully-human monoclonal antibodies in clinical development for the treatment of various diseases and conditions including elevated LDL cholesterol, rheumatoid arthritis, atopic dermatitis, and cancer. We anticipate Phase 2 data from some of these programs in 2011."

"We entered 2011 in a strong financial position to support our development and commercialization activities," commented Murray A. Goldberg, Chief Financial Officer, "with approximately $627 million in cash and securities, following a successful public offering of Common Stock in October 2010."

Clinical Programs Update

VEGF Trap-Eye (aflibercept ophthalmic solution) – Ophthalmologic Diseases

VEGF Trap-Eye is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PLGF), proteins that are involved in the abnormal growth of new blood vessels. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States. Bayer HealthCare LLC has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye.

Phase 3 studies in wet age-related macular degeneration

In November 2010, Regeneron and Bayer Healthcare reported positive one-year data from two Phase 3 studies (VIEW 1 and VIEW 2) evaluating VEGF Trap-Eye in patients with the neovascular form of age-related macular degeneration (wet AMD). Based on these results, Regeneron plans to submit a Biologics License Application to the Food and Drug Administration (FDA) for marketing approval in the U.S. in the first half of 2011. In addition, Bayer Healthcare intends to submit regulatory applications in the first half of 2011 for marketing approval in Europe.

In VIEW 1 and VIEW 2, VEGF Trap-Eye was administered either monthly or every two months, and compared to monthly doses of ranibizumab, which is the current standard of care in wet AMD. In these studies, all regimens of VEGF Trap-Eye including VEGF Trap-Eye dosed every two months successfully met the primary endpoint of non-inferiority compared to ranibizumab dosed every month. The primary endpoint was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. At least 94% of patients in every VEGF Trap-Eye group, including those dosed every two months, as well as those receiving ranibizumab dosed monthly, maintained visual acuity over 52 weeks. Visual acuity was measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity. Maintenance of vision was defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS eye chart.

In VIEW 1 and VIEW 2, a generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. 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.

Phase 3 studies in central retinal vein occlusion

In December 2010, Regeneron and Bayer Healthcare reported positive initial results from the COPERNICUS study, the first of two Phase 3 studies evaluating VEGF Trap-Eye in central retinal vein occlusion (CRVO). Patients received six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2.0 milligrams (mg) or sham control injections. In COPERNICUS, VEGF Trap-Eye met the primary endpoint of a statistically significant improvement in vision 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.

Initial results from GALILEO, the second of the two Phase 3 studies in CRVO, are expected in the first half of 2011.

Phase 2 study in diabetic macular edema

In December 2010, Regeneron and Bayer Healthcare reported 52-week results from a Phase 2 study (DA VINCI) comparing treatment with VEGF Trap-Eye to focal laser therapy, the current standard of care, in patients with clinically significant diabetic macular edema (DME). The DME data showed that previously reported visual acuity gains achieved with VEGF Trap-Eye treatment over 24 weeks, the primary endpoint of the study, 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 other month. 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 group versus focal laser).

In DA VINCI, VEGF Trap-Eye was generally well tolerated. 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 included conjunctival hemorrhage, eye pain, ocular redness (hyperemia), and increased intraocular pressure. There were no non-ocular serious adverse events judged by investigators to be drug-related during the first six months of the study and one during the second six months.

Based on these positive results, Regeneron and Bayer Healthcare are discussing plans to initiate Phase 3 studies of VEGF Trap-Eye in DME.

Phase 3 study in choroidal neovascularisation

In January 2011, Regeneron and Bayer HealthCare announced 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 choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia.

ARCALYST® (rilonacept) – Gout

ARCALYST® is a fusion protein that blocks the cytokine interleukin-1 (IL-1). ARCALYST® is currently 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. CAPS is 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.

ARCALYST® is in a Phase 3 clinical development program for the prevention of gout flares in patients initiating uric acid-lowering therapy. In June 2010, the Company announced positive efficacy and safety results from a Phase 3 study (PRE-SURGE 1) in gout patients initiating allopurinol therapy to lower their uric acid levels. Patients 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, $p<0.0001$). ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Injection site reaction, generally considered mild, was the most commonly reported adverse event with ARCALYST®.

Two other studies are ongoing in the Phase 3 program. 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 the Company expects to have initial data from both studies in the first quarter of 2011. Regeneron owns worldwide rights to ARCALYST®.

Aflibercept (VEGF Trap) – Oncology

Aflibercept, also known as VEGF Trap, is a fusion protein that is designed to bind VEGF-A and PLGF, proteins that are involved in the abnormal growth of new blood vessels in solid tumors.

Aflibercept is being developed worldwide by Regeneron and its collaborator, the sanofi-aventis Group, for the potential treatment of solid tumors. Three randomized, double-blind, Phase 3 trials, all of which are fully enrolled, 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. The third trial (VENICE) is evaluating aflibercept as a 1st-line treatment for metastatic, castration-resistant prostate cancer in combination with docetaxel/prednisone.

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 Independent Data Monitoring Committee in mid-2011, with final results anticipated in 2012.

In addition, a randomized Phase 2 study (AFFIRM) is evaluating aflibercept as a 1st-line treatment for metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin). The AFFIRM study is fully enrolled, and initial data are anticipated in the second half of 2011.

Monoclonal Antibodies

Since 2007, Regeneron and sanofi-aventis have collaborated on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune*® technology. During the fourth quarter of 2009, Regeneron and sanofi-aventis expanded and extended their collaboration with the objective to advance an average of four to five antibodies into clinical development each year between 2010 and 2017. The following eight antibody candidates are currently in clinical development under the collaboration:

REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), a novel target for LDL cholesterol ("bad cholesterol") reduction, has been evaluated in Phase 1 studies using both intravenous and subcutaneous routes of administration. REGN727 is being studied as a single agent and in combination with statin therapy. Phase 2 studies have been initiated in patients with hypercholesterolemia.

REGN88, an antibody to the interleukin-6 receptor (IL-6R), is in a Phase 2/3 study in rheumatoid arthritis and a Phase 2 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.

REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, is in a Phase 1 study in patients with advanced malignancies.

REGN668, an antibody to the interleukin-4 receptor (IL-4R), a target for allergic and immune conditions, has completed Phase 1 testing in healthy volunteers. A Phase 1b study in patients with atopic dermatitis is underway and a Phase 2 study in asthma is planned.

REGN910, an antibody to angiopoietin-2 (ANG2), a novel angiogenesis target, is in a Phase 1 study in oncology.

REGN475, an antibody to nerve growth factor (NGF), has completed a Phase 2 trial in 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.

REGN728 and *REGN846*, whose targets remain undisclosed, have entered clinical development.

Financial Results

The Company's total revenues increased to $133.7 million in the fourth quarter of 2010 from $96.8 million in the same quarter of 2009 and to $459.1 million for the full year 2010 from $379.3 million for the full year 2009. The increases were primarily due to higher collaboration revenue in 2010 in connection with the Company's antibody collaboration with sanofi-aventis. In addition, the increase in the fourth quarter of 2010 was partly due to the recognition of $20.0 million in substantive milestone payments from Bayer HealthCare.

Net product sales of ARCALYST® in the fourth quarter of 2010 were $5.3 million, compared to $5.0 million during the same period of 2009. The Company recognized $25.3 million of net product sales for the full year 2010, which included $20.5 million of ARCALYST® net product sales made during 2010 and $4.8 million of previously deferred net product sales. In 2009, the Company recognized $18.4 million of ARCALYST® net product sales.

The Company's total operating expenses increased to $146.5 million in the fourth quarter of 2010 from $136.2 million in the same quarter of 2009, and to $556.5 million for the full year 2010 from $453.4 million for the full year 2009. The increases were primarily due to higher research and development expenses arising from the Company's expanding research and development activities in 2010 and related higher employee headcount, principally in connection with the sanofi-aventis antibody collaboration. Research and development expenses for the full year 2010 rose to $489.2 million from $398.8 million in 2009.

The Company had a net loss of $14.6 million, or $0.17 per share (basic and diluted), for the fourth quarter of 2010 compared with a net loss of $36.5 million, or $0.46 per share (basic and diluted), for the fourth quarter of 2009. The Company had a net loss of $104.5 million, or $1.26 per share (basic and diluted), for the full year 2010 compared with a net loss of $67.8 million, or $0.85 per share (basic and diluted), for the full year 2009.

In October 2010, the Company completed a public offering of 6,325,000 shares of Common Stock and received net proceeds of $174.8 million. At December 31, 2010, cash and marketable securities totaled $626.9 million (including $7.5 million of restricted cash and marketable securities) compared with $390.0 million (including $1.6 million of restricted cash) at December 31, 2009.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration and central retinal vein occlusion), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties and actual events or results may differ materially from these forward-looking statements. These risks and uncertainties include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	December 31, 2010	December 31, 2009
ASSETS		
Cash, restricted cash, and marketable securities	626,939	$ 390,010
Receivables	93,112	65,568
Property, plant, and equipment, net	347,450	259,676
Other assets	21,931	25,948
Total assets	$ 1,089,432	$ 741,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	$ 61,008	$ 52,990
Deferred revenue	340,579	182,428
Facility lease obligations	160,030	109,022
Stockholders' equity	527,815	396,762
Total liabilities and stockholders' equity	$ 1,089,432	$ 741,202

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended December 31,		For the year ended December 31,	
	2010	**2009**	**2010**	**2009**
Revenues				
Collaboration revenue	$ 117,047	$ 80,582	$ 386,725	$ 314,457
Technology licensing	10,038	10,013	40,150	40,013
Net product sales	5,269	5,000	25,254	18,364
Contract research and other	1,321	1,205	6,945	6,434
	133,675	96,800	459,074	379,268
Expenses				
Research and development	125,212	118,790	489,252	398,762
Selling, general, and administrative	20,641	17,031	65,201	52,923
Cost of goods sold	599	387	2,093	1,686
	146,452	136,208	556,546	453,371
Loss from operations	(12,777)	(39,408)	(97,472)	(74,103)
Other income (expense)				
Investment income	638	553	2,122	4,488
Interest expense	(2,458)	(1,756)	(9,118)	(2,337)
	(1,820)	(1,203)	(6,996)	2,151
Net loss before income tax benefit	(14,597)	(40,611)	(104,468)	(71,952)
Income tax benefit		(4,122)		(4,122)
Net loss	$ (14,597)	$ (36,489)	$ (104,468)	$ (67,830)
Net loss per share amounts, basic and diluted	$ (0.17)	$ (0.46)	$ (1.26)	$ (0.85)
Weighted average shares outstanding, basic and diluted	87,405	80,137	82,926	79,782

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 4/27/2011

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 27, 2011 (April 27, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On April 27, 2011, Regeneron Pharmaceuticals, Inc. and Bayer HealthCare issued a press release reporting positive top-line results for VEGF Trap-Eye (aflibercept ophthalmic solution) in the Phase 3 GALILEO study in patients with macular edema due to central retinal vein occlusion. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release Reporting Positive Results for VEGF Trap-Eye in Second Phase 3 Study in Central Retinal Vein Occlusion, dated April 27, 2011.

SIGNATURES

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 hereunto duly authorized.

Date: April 27, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance and Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Exhibit Index

Number	Description
99.1	Press Release Reporting Positive Results for VEGF Trap-Eye in Second Phase 3 Study in Central Retinal Vein Occlusion, dated April 27, 2011

REGENERON

For Immediate Release

Press Release

Regeneron and Bayer Report Positive Results for VEGF Trap-Eye in Second Phase 3 Study in Central Retinal Vein Occlusion

Regulatory applications for marketing approval in the US planned in second-half of 2011 and in Europe in 2012

Tarrytown, NY, USA, and Berlin, Germany, April 27, 2011 -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Bayer HealthCare today announced positive top-line results for VEGF Trap-Eye (aflibercept ophthalmic solution) in the Phase 3 GALILEO study in patients with macular edema due to central retinal vein occlusion (CRVO). The positive results from the GALILEO study confirm the results of the similarly designed Phase 3 COPERNICUS study that were announced in December 2010.

In GALILEO, the primary endpoint at week 24 was achieved: 60.2 percent of patients receiving monthly VEGF Trap-Eye 2 milligrams (mg) gained at least 15 letters of vision from baseline, compared to 22.1 percent of patients receiving sham injections ($p<0.0001$). The key secondary endpoint of the study was also met: patients receiving VEGF Trap-Eye 2mg monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$).

"After reporting positive results from the VIEW 1 and VIEW 2 Phase 3 studies for the treatment of the neovascular form of age-related macular degeneration, or wet AMD, we are very pleased to now also have two positive Phase 3 trials with VEGF Trap-Eye in central retinal vein occlusion," said Kemal Malik, M.D., Head of Global Development and member of the Bayer HealthCare Executive Committee.

"With two Phase 3 trials showing impressive improvement in vision relative to control, VEGF Trap-Eye has the potential to provide patients and physicians a new treatment option for central retinal vein occlusion," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories.

As in the COPERNICUS trial, VEGF Trap-Eye was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. The incidence of ocular serious adverse events was higher in the sham group compared to the active treatment arm (8.8% vs 2.9%).

Regeneron intends to submit a regulatory application for marketing approval in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in Europe in 2012.

Detailed results of the GALILEO study will be presented at the EURETINA Congress in London in May, 2011.

About the Phase 3 CRVO Program
Patients in the COPERNICUS (Controlled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) and the almost identical GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) studies received six monthly injections of either VEGF Trap-Eye at a dose of 2mg or sham injections.

Patients in both trials were randomized in a 3:2 ratio with 114 patients randomized to receive VEGF Trap-Eye and 73 randomized to the control arm in COPERNICUS and 104 patients randomized to receive VEGF Trap-Eye and 68 randomized to the control arm in GALILEO. At the end of the initial six months, all patients randomized to VEGF Trap-Eye are dosed on a PRN (as needed) basis for another six months. In the COPERNICUS trial, patients randomized to sham injections in the first six months were eligible to cross over to VEGF Trap-Eye PRN dosing in the second six months. During the second six months of the studies, all patients are eligible for rescue laser treatment. Visual acuity is measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

Phase 3 GALILEO Study Results
In the GALILEO study, 60.2 percent of patients receiving VEGF Trap-Eye 2mg monthly gained at least 15 letters of vision from baseline, compared to 22.1 percent of patients receiving sham injections ($p<0.0001$), the primary endpoint of the study. Patients receiving VEGF Trap-Eye 2mg monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$), a secondary endpoint.

VEGF Trap-Eye was generally well tolerated and 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 2.9 percent and were more frequent in the control group (8.8 percent). The most frequently reported adverse events overall in the VEGF Trap-Eye arm were eye pain, conjunctival hemorrhage and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduction of visual acuity. The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. The most frequent non-ocular adverse events were headache and nasopharyngitis. There were no deaths in the study.

About Central Retinal Vein Occlusion (CRVO)
Over 100,000 people in the United States and more than 66,000 people in key European countries are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to a back up of blood and fluid in the retina. This causes retinal injury and loss of vision. The retina can also become "ischemic" (starved for oxygen), resulting in the growth of new, inappropriate blood vessels that can cause further vision loss and more serious complications. Release of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and inappropriate new vessel growth. It is believed that anti-VEGF treatment may help decrease vascular permeability and edema and prevent the inappropriate growth of new blood vessels in the retina in patients with CRVO.

About VEGF Trap-Eye
VEGF Trap-Eye is a fully human fusion protein, consisting of soluble VEGF receptors 1 and 2, that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. VEGF Trap-Eye is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Bayer HealthCare and Regeneron are collaborating on the global development of VEGF Trap-Eye for the treatment of the neovascular form of age related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and other eye diseases and disorders.

Regeneron submitted a Biologics License Application (BLA) for marketing approval in wet AMD in the U.S. in February 2011 and received a Priority Review designation. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011. Bayer plans to file regulatory submissions in Europe in the second quarter of 2011.

In April 2011, Bayer HealthCare and Regeneron announced the initiation of a Phase 3 program in DME.

Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally the profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular edema), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of more than EUR 16.913 billion (2010), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55.700 employees and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

Regeneron Forward-Looking Statements

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that may be superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

Bayer Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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Electronic Patent Application Fee Transmittal	
Application Number:	16397267
Filing Date:	29-Apr-2019
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Filer:	Karl Bozicevic/Kimberly Zuehlke
Attorney Docket Number:	REGN-008CIPCON5
Filed as Large Entity	
Filing Fees for Utility under 35 USC 111(a)	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
		Total in USD ($)		**240**

Electronic Acknowledgement Receipt	
EFS ID:	40026253
Application Number:	16397267
International Application Number:	
Confirmation Number:	8135
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Customer Number:	96387
Filer:	Karl Bozicevic/Kimberly Zuehlke
Filer Authorized By:	Karl Bozicevic
Attorney Docket Number:	REGN-008CIPCON5
Receipt Date:	16-JUL-2020
Filing Date:	29-APR-2019
Time Stamp:	18:13:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$240
RAM confirmation Number	E20207FI14310791
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	0725US06_2020-07-16_Supp_IDS_trans_REGN-008CIPCON5.pdf	51813 ce7a69af2beb32febc3c34838873e77d310fecea	no	2
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Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	0725US06__2020-07-16_Supp_IDS_SB08A_REGN-008CIPCON5.pdf	63978 3dd2daa46283e643f9bbd4d1897fab36d2e00824	no	5
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Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	WO2005000895A2.pdf	2338182 6363e90be1b6d4d2492328637 8ef404ecffe18c3	no	38
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4	Foreign Reference	WO2004106378A2.pdf	1507654 b6c832b47fd56959cb880da99e6703a41bf742cc	no	23
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5	Non Patent Literature	01_Benz_May_2007.pdf	46129 dff86fc070ae43858a162bc440b012b07665a2f9	no	2
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6	Non Patent Literature	02_Do_May_2007.pdf	53639 d211e1d8d8063e474ab9ec77238f8a5a33fbdb06	no	2
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38	Non Patent Literature	34_20090430_REGENERON_PHARMACEUTICALS_INC_10-Q_4_30.pdf	1262748 64632b48b21ea7789c60d93cd35101c4149910c9	no	87
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Information:					
		Total Files Size (in bytes):	77134681		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronically Filed

INFORMATION DISCLOSURE STATEMENT	Attorney Docket No.	REGN-008CIPCON5
	Confirmation No.	8135
	First Named Inventor	George D. Yancopoulos
	Application Number	16/397,267
	Filing Date	April 29, 2019
	Group Art Unit	1647
Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Examiner Name	Jon McClelland Lockard
	Title: "*Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders*"	

Sir:

Applicant submits herewith documents which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56. This submission is not intended to constitute an admission that any document referred to therein is "prior art" for this invention unless specifically designated as such. A listing of the documents is shown on enclosed Form PTO/SB/08A and copies of the foreign patents and non-patent literature are also enclosed.

The publications discussed herein are provided to comply with the duty to disclose in accordance with 37 C.F.R. § 1.56. However, nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed

The Examiner is requested to make the documents listed on the enclosed PTO/SB/08A of record in this application. Applicant would appreciate the Examiner initialing and returning the initialed copy of form PTO/SB/08A, indicating the documents cited therein have been considered and made of record herein.

Statements

☒ **No statement**

☐ **PTA Statement under 37 CFR § 1.704(d)(1):** Each item of information contained in the information disclosure statement filed herewith:

(i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by

any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

☐ **IDS Statement under 37 CFR § 1.97(e)(1):** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ **IDS Statement under 37 CFR § 1.97(e)(2):** No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

Fees

☐ No fee is believed to be due.

☒ The appropriate fee set forth in 37 C.F.R. §1.17(p) accompanies this information disclosure statement.

The Commissioner is hereby authorized to charge any underpayment of fees up to a strict limit of $3,000.00 beyond that authorized on the credit card, but not more than $3,000.00 in additional fees due with any communication for the above referenced patent application, including but not limited to any necessary fees for extensions of time, or credit any overpayment of any amount to Deposit Account No. 50-0815, order number REGN-008CIPCON5.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 16 July 2020

By: /Karl Bozicevic, Reg. No. 28,807/
Karl Bozicevic
Reg. No. 28,807

BOZICEVIC, FIELD & FRANCIS LLP
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Redwood City, CA 94065
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 5/3/2011

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 3, 2011 (May 3, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On May 3, 2011, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 2011. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated May 3, 2011.

SIGNATURES

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 hereunto duly authorized.

Date: May 3, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance and Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Exhibit Index

Number	Description
99.1	Press Release dated May 3, 2011

REGENERON

For Immediate Release

Press Release

Regeneron Reports First Quarter 2011 Financial and Operating Results

Tarrytown, New York (May 3, 2011) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2011 and provided an update on development programs and upcoming milestones.

Clinical Programs Update

VEGF Trap-Eye (aflibercept ophthalmic solution) – Ophthalmologic Diseases

VEGF Trap-Eye is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PlGF), proteins that are involved in the abnormal growth of new blood vessels. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States. Bayer HealthCare LLC has rights to market VEGF Trap-Eye outside the U.S., where the companies will share equally in profits from any future sales of VEGF Trap-Eye.

In February 2011, Regeneron submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for VEGF Trap-Eye for the treatment of the neovascular form of age-related macular degeneration (wet AMD). In April 2011, the FDA accepted the BLA for filing and granted the Company's request for Priority Review. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011.

Also in February 2011, data from the Phase 3 VIEW 1 and VIEW 2 trials of VEGF Trap-Eye in patients with wet AMD and the Phase 3 COPERNICUS trial in macular edema due to central retinal vein occlusion (CRVO) were presented at the Bascom Palmer Eye Institute's Angiogenesis, Exudation and Degeneration 2011 meeting. Results of the Phase 2 DA VINCI trial of VEGF Trap-Eye in diabetic macular edema (DME) were also presented.

In April 2011, Regeneron and Bayer HealthCare announced positive top-line results for VEGF Trap-Eye in the Phase 3 GALILEO study in patients with macular edema due to CRVO. The positive results from the GALILEO study confirmed the results of the similarly designed COPERNICUS study that were announced in December 2010. In GALILEO, the primary endpoint at week 24 was achieved: 60.2% of patients receiving 2 milligrams (mg) of VEGF Trap-Eye monthly gained at least 15 letters of vision from baseline, compared to 22.1% of patients receiving sham injections ($p<0.0001$). The key secondary endpoint of the study was also met: patients receiving 2 mg of VEGF Trap-Eye monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$). As in the COPERNICUS trial, VEGF Trap-Eye was generally well tolerated in the GALILEO study and 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 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the VEGF Trap-Eye arm were eye pain, conjunctival hemorrhage, and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduction of visual acuity. Detailed results of the GALILEO study will be presented at the EURETINA Congress in London in May 2011.

Based on these positive results, Regeneron intends to submit a regulatory application for marketing approval for VEGF Trap-Eye in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in Europe in 2012.

In April 2011, Regeneron and Bayer Healthcare announced that Bayer HealthCare has initiated the Phase 3 VIVID-DME study of VEGF Trap-Eye in DME in Australia. The trial will also be conducted in Europe and Japan. Regeneron intends to commence a second Phase 3 study (VISTA-DME) in DME later in 2011 in the U.S., Canada, and other countries.

ZALTRAP™ (aflibercept) – Oncology

ZALTRAP™, also known as VEGF Trap, is a fusion protein that is designed to bind VEGF-A, VEGF-B, and PlGF, proteins that are involved in the abnormal growth of new blood vessels in solid tumors. ZALTRAP™ is being developed worldwide by Regeneron and its collaborator, the sanofi-aventis Group, for the potential treatment of solid tumors.

In April 2011, Regeneron and sanofi-aventis announced that the Phase 3 VELOUR trial evaluating ZALTRAP™ in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan] versus a regimen of FOLFIRI plus placebo met its primary endpoint of improving overall survival (OS) in the second-line treatment of metastatic colorectal cancer (mCRC). Full results will be presented at an upcoming medical meeting. The most frequent adverse events reported with ZALTRAP™ in combination with FOLFIRI were diarrhea, asthenia/fatigue, stomatitis and ulceration, nausea, infection, hypertension, gastrointestinal and abdominal pains, vomiting, decreased appetite, decreased weight, epistaxis, alopecia, and dysphonia.

Based upon these positive findings, Regeneron and sanofi-aventis plan to submit regulatory applications for marketing approval of ZALTRAP™ for the second-line treatment of mCRC to the FDA and the European Medicines Agency in the second half of 2011.

In February 2011, Regeneron and sanofi-aventis announced results from the Phase 3 VITAL trial evaluating ZALTRAP™ for the second-line treatment of non-small cell lung cancer (NSCLC). The data showed that adding ZALTRAP™ to the chemotherapy drug docetaxel did not meet the pre-specified criteria for the primary endpoint of improvement in overall survival compared with a regimen of docetaxel plus placebo (HR=1.01, CI: 0.868 to 1.174). The addition of ZALTRAP™ to docetaxel demonstrated activity as measured by key secondary endpoints of the study: progression free survival (PFS) (HR=0.82, CI: 0.716 to 0.937) and an overall objective response rate (ORR) of 23.3% in the ZALTRAP™ arm compared to 8.9% in the placebo arm. The types and frequencies of adverse events reported in the ZALTRAP™ treatment arm were generally consistent with those reported in previous studies with anti-VEGF agents. The most frequent Grade 3/4 adverse events included fatigue, stomatitis, disease progression, and hypertension.

Another randomized, double-blind Phase 3 trial (VENICE), which is fully enrolled, is evaluating ZALTRAP™ as a first-line treatment for metastatic, castration-resistant prostate cancer in combination with docetaxel/prednisone. Based on projected event rates, an interim analysis of the VENICE study is expected to be conducted by an Independent Data Monitoring Committee in mid-2011, and final results are anticipated in 2012.

In addition, a randomized Phase 2 study (AFFIRM) is evaluating ZALTRAP™ as a first-line treatment for metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin). The AFFIRM study is fully enrolled, and initial data are anticipated in the second half of 2011.

ARCALYST® (rilonacept) – Gout

ARCALYST® is a fusion protein that blocks the cytokine interleukin-1 (IL-1). ARCALYST® is currently available for prescription in the U.S. 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. CAPS is 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.

In February 2011, Regeneron reported the results of its second and third Phase 3 studies of ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy and announced that, based on these studies and a previously reported Phase 3 study, the Company plans to submit a supplemental BLA for U.S. regulatory approval of ARCALYST® in this setting in mid-2011. The Company reported that in the PRE-SURGE 2 efficacy study in gout patients initiating allopurinol therapy, ARCALYST® met the primary and all secondary study endpoints. The primary endpoint was the number of gout flares per patient over the 16-week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of either 160 mg or 80 mg had a 72% decrease in mean number of gout flares compared to the placebo group ($p<0.0001$). These results were consistent with those in the identical Phase 3 efficacy study (PRE-SURGE 1) reported in June 2010. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. The most frequently reported adverse event was upper respiratory tract infection (15.5% with ARCALYST® 160 mg, 12.2% with ARCALYST® 80 mg, and 12.2% with placebo).

Regeneron also announced that in the third Phase 3 study (RE-SURGE), which evaluated the safety of ARCALYST® versus placebo over 16 weeks, ARCALYST® was generally well tolerated, and the safety profile was consistent with that reported in the PRE-SURGE 1 and PRE-SURGE 2 studies. RE-SURGE evaluated 1,315 patients who were at risk for gout flares while initiating or taking uric acid-lowering drug treatment. Other than injection site reactions, the incidence of treatment-emergent adverse events was generally well-balanced among the 985 patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg and the 330 patients who received placebo. Injection site reactions, usually considered mild, were reported more commonly with ARCALYST® (15.2%) than with placebo (3.3%). Overall, the cumulative rate of infections was 20.1% in patients treated with ARCALYST® and 19.1% in placebo patients. Serious infections were reported in 0.5% of patients treated with ARCALYST® and 0.9% of placebo patients. Deaths were reported for 0.3% of patients treated with ARCALYST® and 0.9% of placebo patients.

In the RE-SURGE study, ARCALYST® also met all secondary endpoints, which evaluated efficacy, over the 16 week treatment period ($p<0.0001$). These included the number of gout flares per patient, the proportion of patients who experienced two or more flares, and the proportion of patients who experienced at least one gout flare during the study period.

Regeneron owns worldwide rights to ARCALYST®.

Monoclonal Antibodies

Since 2007, Regeneron and sanofi-aventis have collaborated on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune*® technology. During the fourth quarter of 2009, Regeneron and sanofi-aventis expanded and extended their collaboration with the objective to advance an average of four to five antibodies into clinical development each year between 2010 and 2017. The following eight antibody candidates are currently in clinical development under the collaboration:

REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), a novel target for LDL cholesterol ("bad cholesterol") reduction, has been evaluated in Phase 1 studies using both intravenous and subcutaneous routes of administration. REGN727 is being studied as a single agent and in combination with statin therapy. Phase 2 studies have been initiated in combination with statins in patients with hypercholesterolemia.

REGN88, an antibody to the interleukin-6 receptor (IL-6R), is in a Phase 2/3 study in rheumatoid arthritis and a Phase 2 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 mid-2011.

REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, is in a Phase 1 study in patients with advanced malignancies.

REGN668, an antibody to the interleukin-4 receptor (IL-4R), a target for allergic and immune conditions, has completed Phase 1 testing in healthy volunteers. A Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma are underway.

REGN910, an antibody to angiopoietin-2 (ANG2), a novel angiogenesis target, is in a Phase 1 study in an oncology setting.

REGN475, an antibody to nerve growth factor (NGF), has completed a Phase 2 trial in 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.

REGN728 and *REGN846*, whose targets remain undisclosed, have entered clinical development.

Financial Results

The Company's total revenues increased to $112.2 million in the first quarter of 2011 from $103.5 million in the same quarter of 2010. The increases were primarily due to higher collaboration revenue in the first quarter of 2011 in connection with the Company's antibody collaboration with sanofi-aventis.

Net product sales of ARCALYST® in the first quarter of 2011 were $4.4 million. Net product sales of ARCALYST® in the first quarter of 2010 were $9.9 million, which included $5.1 million of net product sales made during the quarter and $4.8 million of previously deferred net product sales.

The Company's total operating expenses increased to $153.2 million in the first quarter of 2011 from $132.4 million in the same quarter of 2010. The increases were primarily due to higher research and development expenses arising from the Company's expanding research and development activities in 2011 and related higher employee headcount, principally in connection with the sanofi-aventis antibody collaboration. Research and development expenses in the first quarter of 2011 rose to $129.4 million from $117.5 million in the same quarter of 2010.

The Company had a net loss of $43.4 million, or $0.49 per share (basic and diluted), for the first quarter of 2011 compared with a net loss of $30.5 million, or $0.38 per share (basic and diluted), for the first quarter of 2010.

At March 31, 2011, cash and marketable securities totaled $607.6 million (including $7.5 million of restricted cash and marketable securities) compared with $626.9 million (including $7.5 million of restricted cash and marketable securities) at December 31, 2010.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular edema), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that may be superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2010 and Form 10-Q for the quarter ended March 31, 2011. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	March 31, 2011	December 31, 2010
ASSETS		
Cash, restricted cash, and marketable securities	$ 607,582	$ 626,939
Receivables	88,156	93,112
Property, plant, and equipment, net	357,423	347,450
Other assets	21,132	21,931
Total assets	$ 1,074,293	$ 1,089,432
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	$ 65,782	$ 61,008
Deferred revenue	330,269	340,579
Facility lease obligations	160,151	160,030
Stockholders' equity	518,091	527,815
Total liabilities and stockholders' equity	$ 1,074,293	$ 1,089,432

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended March 31,	
	2011	**2010**
Revenues		
Collaboration revenue	$ 97,810	$ 81,758
Technology licensing	7,845	10,038
Net product sales	4,427	9,852
Contract research and other	2,122	1,886
	112,204	103,534
Expenses		
Research and development	129,392	117,471
Selling, general, and administrative	23,411	14,223
Cost of goods sold	382	717
	153,185	132,411
Loss from operations	(40,981)	(28,877)
Other income (expense)		
Investment income	1,037	439
Interest expense	(3,719)	(2,084)
	(2,682)	(1,645)
Net loss before income tax benefit	(43,663)	(30,522)
Income tax benefit	(216)	
Net loss	$ (43,447)	$ (30,522)
Net loss per share amounts, basic and diluted	$ (0.49)	$ (0.38)
Weighted average shares outstanding, basic and diluted	89,162	81,169

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 6/21/2011

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 20, 2011 (June 17, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On June 17, 2011, Regeneron Pharmaceuticals, Inc. issued a press release announcing that the Dermatologic and Ophthalmic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted unanimously to recommend that the FDA approve EYLEA™ (aflibercept ophthalmic solution), also known as VEGF Trap-Eye, for the treatment of the neovascular form of age-related macular degeneration (wet AMD) at a dose of 2 milligrams (mg) every eight weeks, following three initial doses given every four weeks.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated June 17, 2011, Announcing that EYLEA™ (aflibercept ophthalmic solution) Received Unanimous Recommendation for Approval for Treatment of Wet AMD from FDA Advisory Committee.

SIGNATURES

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 hereunto duly authorized.

Date: June 20, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance and Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Exhibit Index

Number	Description
99.1	Press Release, dated June 17, 2011, Announcing that EYLEA™ (aflibercept ophthalmic solution) Received Unanimous Recommendation for Approval for Treatment of Wet AMD from FDA Advisory Committee

REGENERON

For Immediate Release

Press Release

Regeneron Announces EYLEA™ (aflibercept ophthalmic solution) Receives Unanimous Recommendation for Approval for Treatment of Wet AMD from FDA Advisory Committee

Tarrytown, NY (June 17, 2011) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced that the Dermatologic and Ophthalmic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has voted unanimously to recommend that the FDA approve EYLEA™, also known as VEGF Trap-Eye, for the treatment of the neovascular form of age-related macular degeneration (wet AMD) at a dose of 2 milligrams (mg) every eight weeks, following three initial doses given every four weeks.

The committee's recommendation will be considered by the FDA in its review of the Biologics License Application (BLA) for EYLEA, but the committee's recommendation is not binding on the FDA. Regeneron submitted a BLA for marketing approval in wet AMD in the U.S. in February 2011 and received a Priority Review designation. Under Priority Review, the target date for an FDA decision on the EYLEA BLA is August 20, 2011.

"The positive recommendation by the advisory committee is an important step toward providing wet AMD patients with a new treatment option that could potentially reduce the burden that exists with current therapies," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "We look forward to continuing to work with the FDA as it completes its evaluation of the EYLEA BLA."

About EYLEA
Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as age-related macular degeneration, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit vascular permeability and lead to edema.

EYLEA (aflibercept ophthalmic solution), also known as VEGF Trap-Eye, is a fully human fusion protein, consisting of portions of VEGF receptors 1 and 2, that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). EYLEA is a specific and highly potent blocker of these growth factors. EYLEA is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Regeneron and Bayer HealthCare are collaborating on the global development of EYLEA for the treatment of the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and other eye diseases and disorders. Bayer submitted an application for marketing authorization in Europe in wet AMD in June 2011.

The EYLEA wet AMD regulatory submissions are based on the positive results from two Phase 3 trials, the VIEW 1 study and the VIEW 2 study. In these trials, all regimens of EYLEA, including 2 milligrams (mg) of EYLEA dosed every two months (following three loading doses), successfully met the primary endpoint of non-inferiority compared to the current standard of care, ranibizumab 0.5 mg dosed every month. The primary endpoint analysis was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. A generally favorable safety profile was observed for both EYLEA and ranibizumab. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters.

Bayer HealthCare will market EYLEA™ outside the United States, where the companies will share equally the profits from any future sales of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular edema), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

Regeneron Forward Looking Statement
This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that may be superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2010 and Form 10-Q for the quarter ended March 31, 2011. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 8/22/2011

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 22, 2011 (August 22, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

On August 22, 2011, at the American Society of Retina Specialists meeting in Boston, Massachusetts, data from the Phase 3 COPERNICUS Study of the safety, efficacy, and tolerability of repeated intravitreal administration of VEGF Trap-Eye in patients with macular edema secondary to central retinal vein occlusion will be presented by W. Lloyd Clark, M.D. A copy of the slides that will be presented is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Presentation entitled VEGF Trap-Eye in CRVO: 1-year Results of the Phase 3 COPERNICUS Study

SIGNATURES

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 hereunto duly authorized.

Date: August 22, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance and Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Exhibit Index

Number	Description
99.1	Presentation entitled VEGF Trap-Eye in CRVO: 1-year Results of the Phase 3 COPERNICUS Study

COPERNICUS
VEGF Trap-Eye for Central Retinal Vein Occlusion
A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of VEGF Trap-Eye in Subjects with Macular Edema Secondary to Central Retinal Vein Occlusion (CRVO)

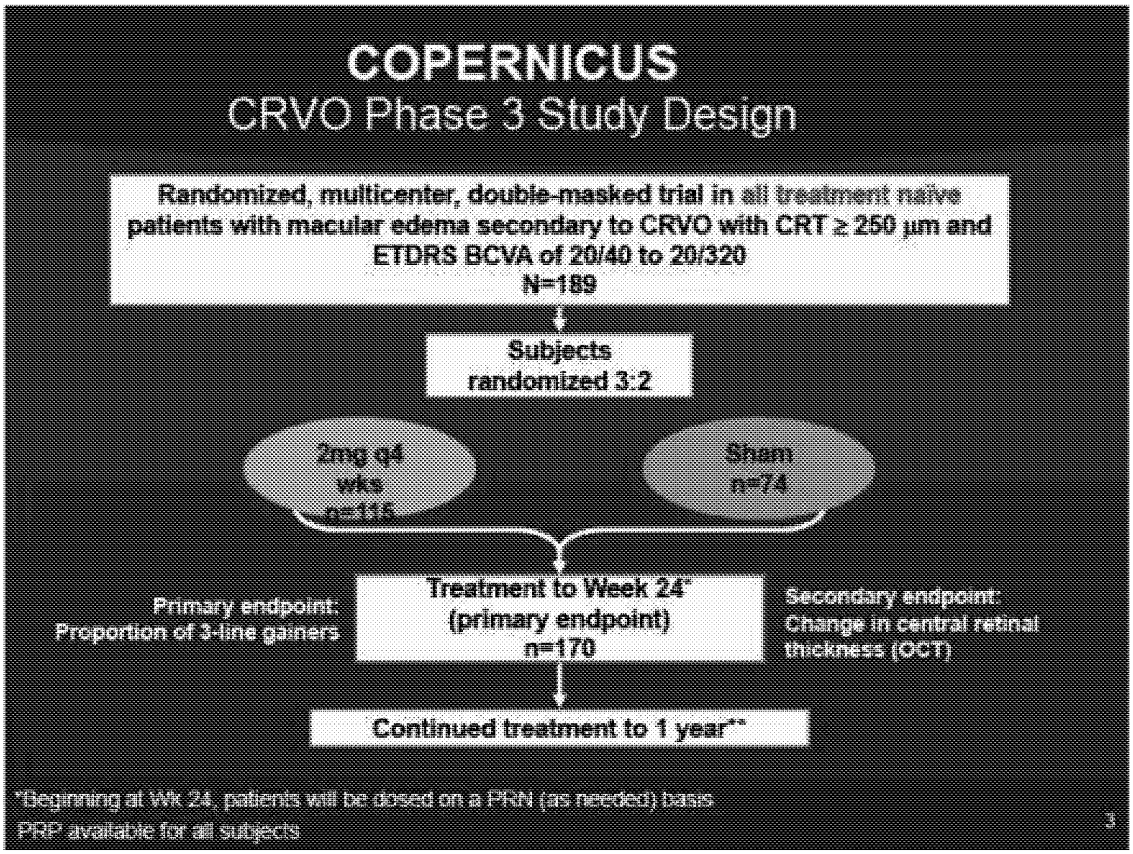
Introduction

- CRVO is an obstruction of the retinal venous system due to thrombus formation
- Prevalence currently of all RVO 0.7–1.6% and increases with age
  - BRVO 3 to 4 times greater incidence versus CRVO

Nonischemic
Up to 50% have visual acuity decrease to ≤ 20/200
< 10% recover normal visual acuity[1,2]
34% progress to ischemic by 3 years; 15% convert in first 4 months[2]
Ischemic
Up to > 90% have final visual acuity 20/200 or worse[1]
37% progress to rubeosis by 4 months[2]

1. Morley et al. Chapter 6.17. In: Ophthalmology. 2003.
2. Denniston et al. Oxford Handbook of Ophthalmology. 2006.

2


COPERNICUS
CRVO Phase 3 Study Design
Randomized, multicenter, double-masked trial in all treatment naive patients with macular edema secondary to CRVO with CRT ≥ 250 µm and ETDRS BCVA of 20/40 to 20/320
N=189
Subjects randomized 3:2
2mg q4 wks n=115
Sham n=74
Primary endpoint: Proportion of 3-line gainers
Treatment to Week 24* (primary endpoint) n=170
Secondary endpoint: Change in central retinal thickness (OCT)
Continued treatment to 1 year**
*Beginning at Wk 24, patients will be dosed on a PRN (as needed) basis
PRP available for all subjects
3

COPERNICUS
Key Exclusion Criteria

- Treatment naive patients
- Previous use of intraocular or periocular corticosteroids in the study eye
- 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

4

COPERNICUS
Patient Disposition

	Sham	VTE 2q4
Randomized	74	115
Received Study Medication	74 (100%)	114 (99.1%)*
Completed Week 24	60 (81.1%)	110 (95.7%)
Discontinuation Before Wk 24	14 (18.9%)	5 (4.3%)
Withdrawal Of Consent^	1 (1.4%)	3 (2.6%)
Protocol Deviation^	1 (1.4%)	0
Adverse Event^	3 (4.1%)	0
Death^	2 (2.7%)	0
Lost To Follow-Up	2 (2.7%)	1 (0.9%)
Treatment Failure	4 (5.4%)	0
Other†	1 (1.4%)	1 (0.9%)

*One patient was randomize but not treated after a retinal tear was identified at Visit 2.
^ Sham: VA Reduced 2q4: Lung cancer, unknown x2
^ Sham: Bilateral CRVO
^ Sham: Neovascular glaucoma, retinal tear, vitreous hemorrhage/NVG
^ Sham: MI and arrhythmia
† Sham: Lack of efficacy 2q4: patient never treated

5

COPERNICUS
Baseline Demographics

	Sham	VTE 2q4
n (full analysis set)	73	114
Age: years (SD)	67.5 (14.29)	65.5 (13.57)
Gender		
Women (%)	35 (48%)	45 (39%)
Men (%)	38 (52%)	69 (61%)
Race (%)		
White	59 (80.8%)	88 (77.2%)
Black	5 (6.8%)	5 (4.4%)
Asian	2 (2.7%)	7 (6.1%)
American Indian/Alaska Native	0	2 (1.8%)
Native Hawaiian/Pacific Islander	1 (1.4%)	0
Not Reported/Multi racial	6 (8.2%)	12 (10.5%)

6

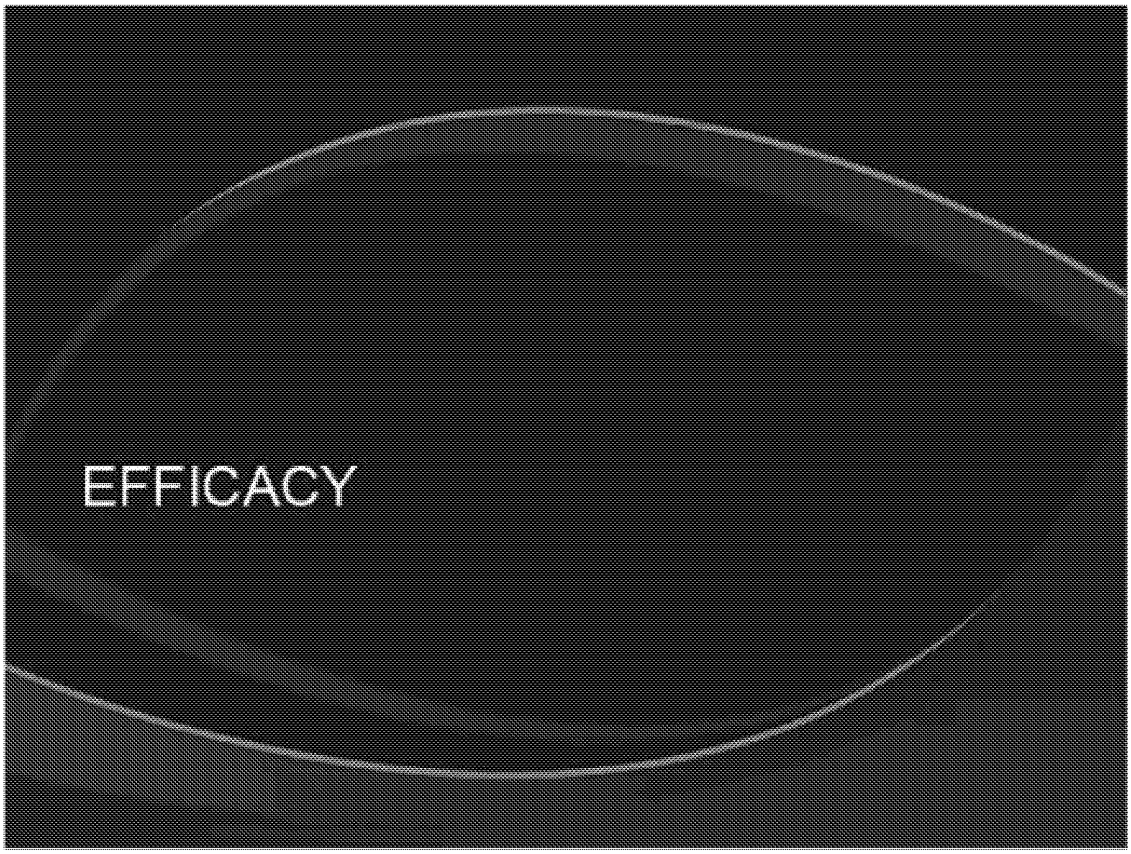
COPERNICUS
Baseline Disease Characteristics

	Sham	VTE 2q4
n (full analysis set)	73	114
ETDRS BCVA letter score (SD) Snellen Equivalent	48.9 (14.4) 20/126	50.7 (13.9) 20/100
BCVA > 20/200 (%)	55 (75.3)	86 (75.4)
BCVA ≤ 20/200 (%)	18 (24.7)	28 (24.6)
Central Retinal Thickness µm (SD)	672.4 (245.3)	661.7 (237.4)
Baseline perfusion status n (%)		
Perfused*	50 (68.5%)	80 (70.2%)
Non-perfused	12 (16.4%)	14 (12.3%)
Indeterminate	10 (13.7%)	18 (15.8%)
Missing	1 (1.4%)	2 (1.8%)

*Less than 10 DA of non perfusion

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 5138

Samsung Bioepis Exhibit 1017, pg. 5138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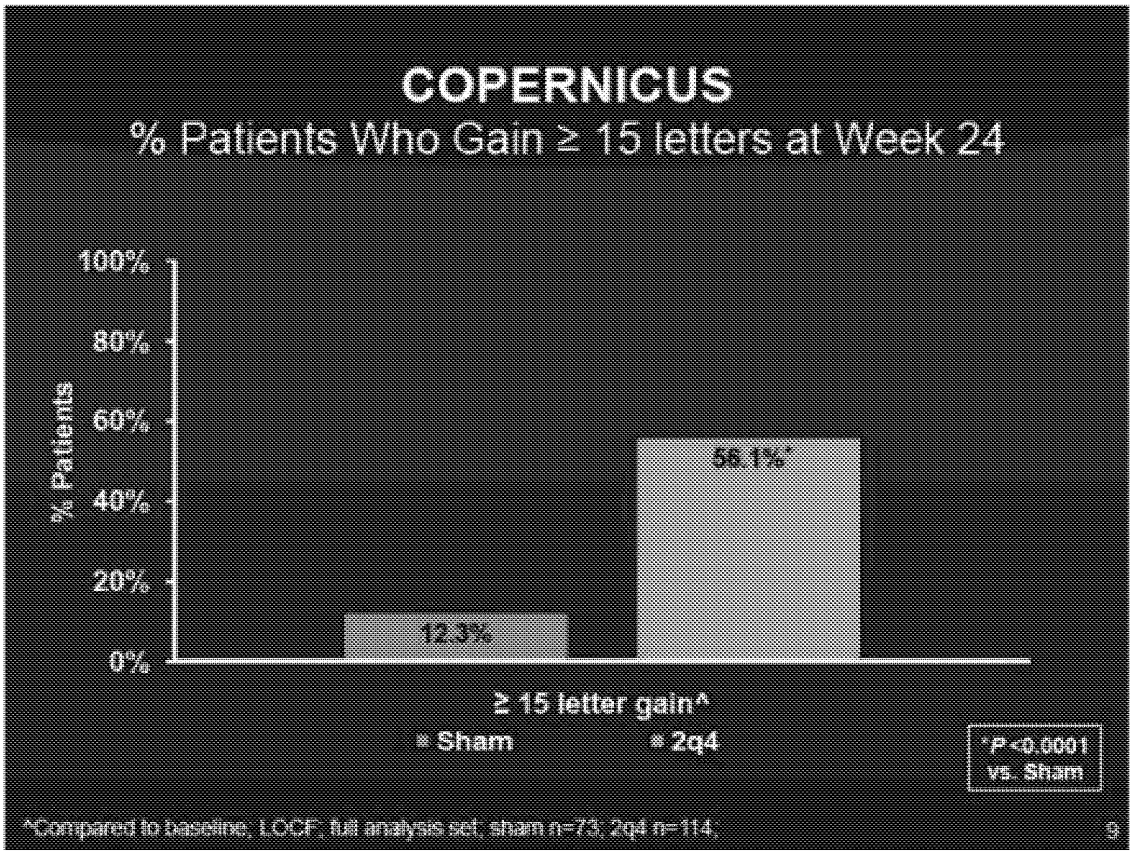
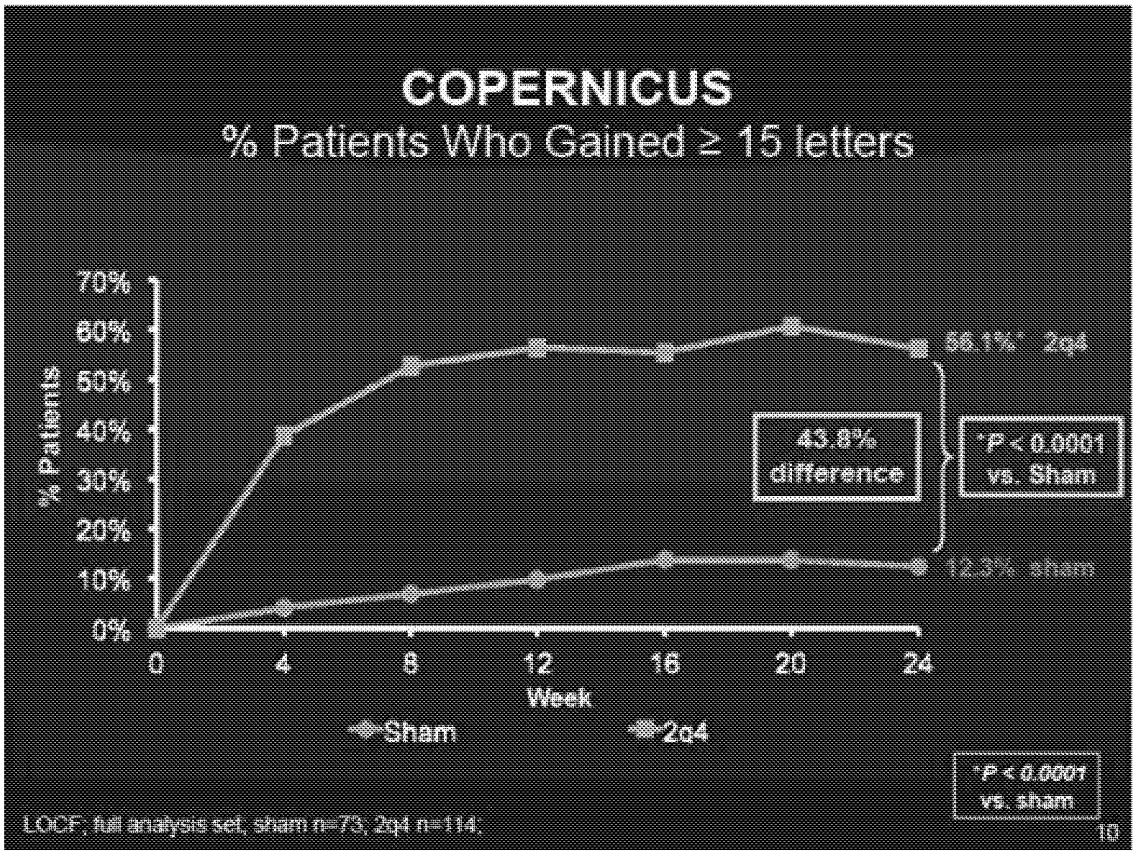
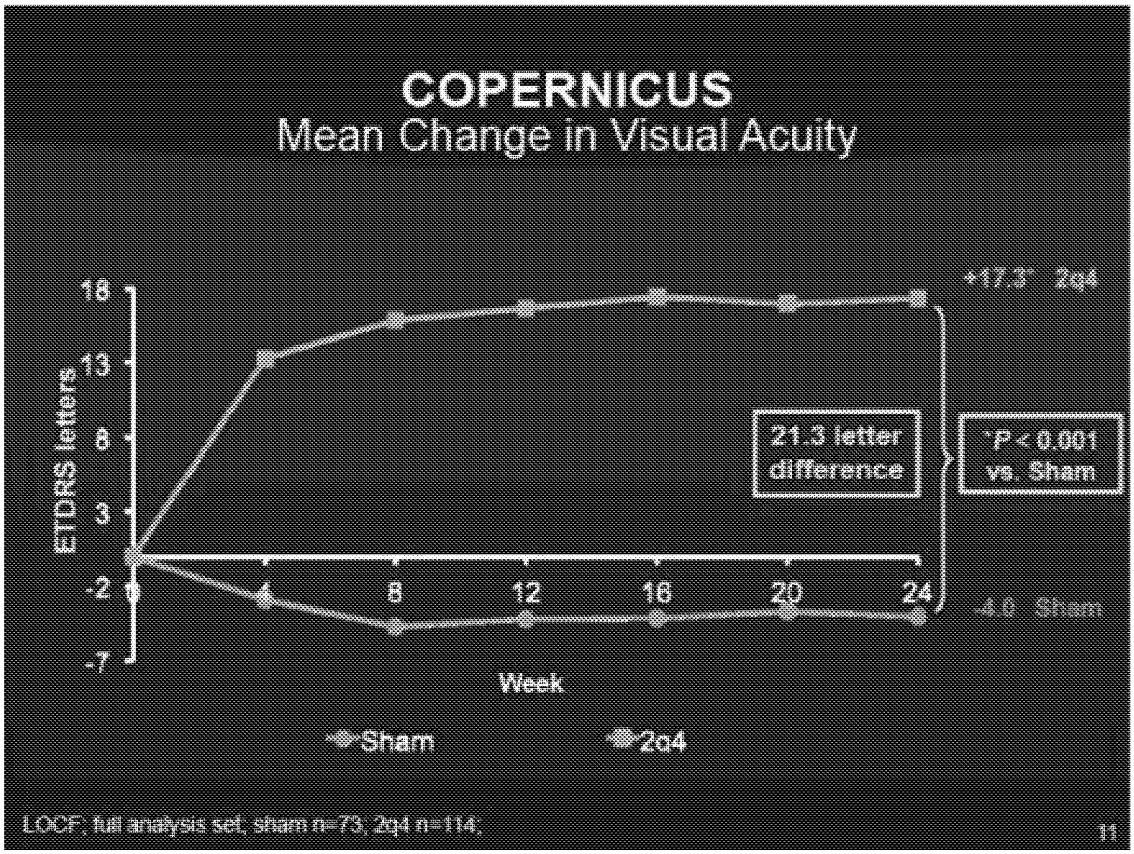
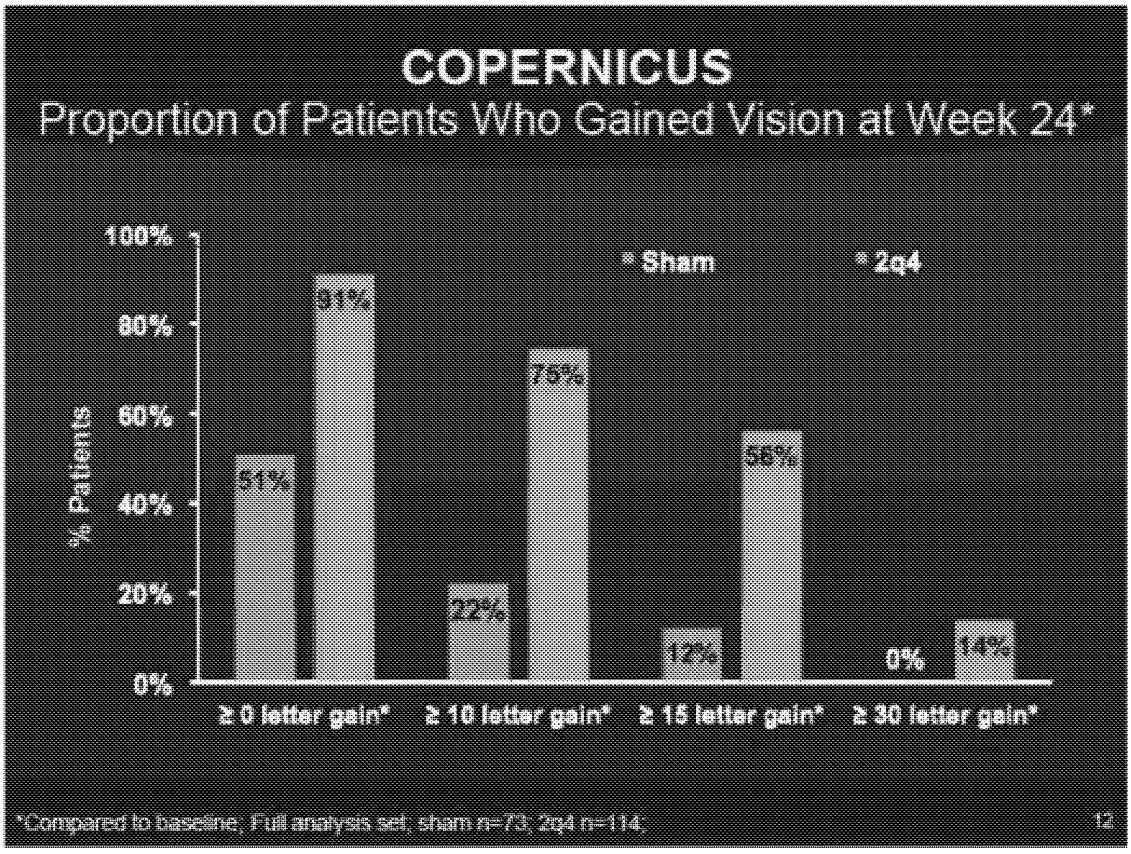
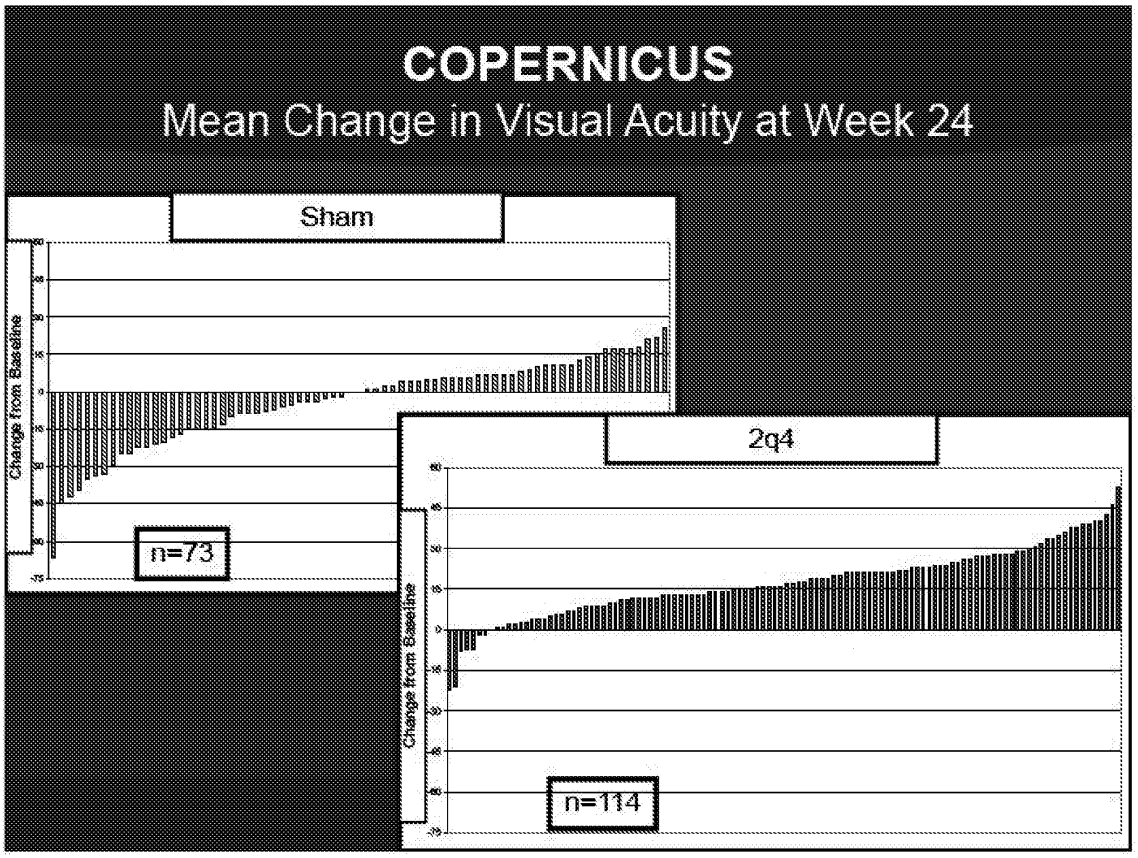
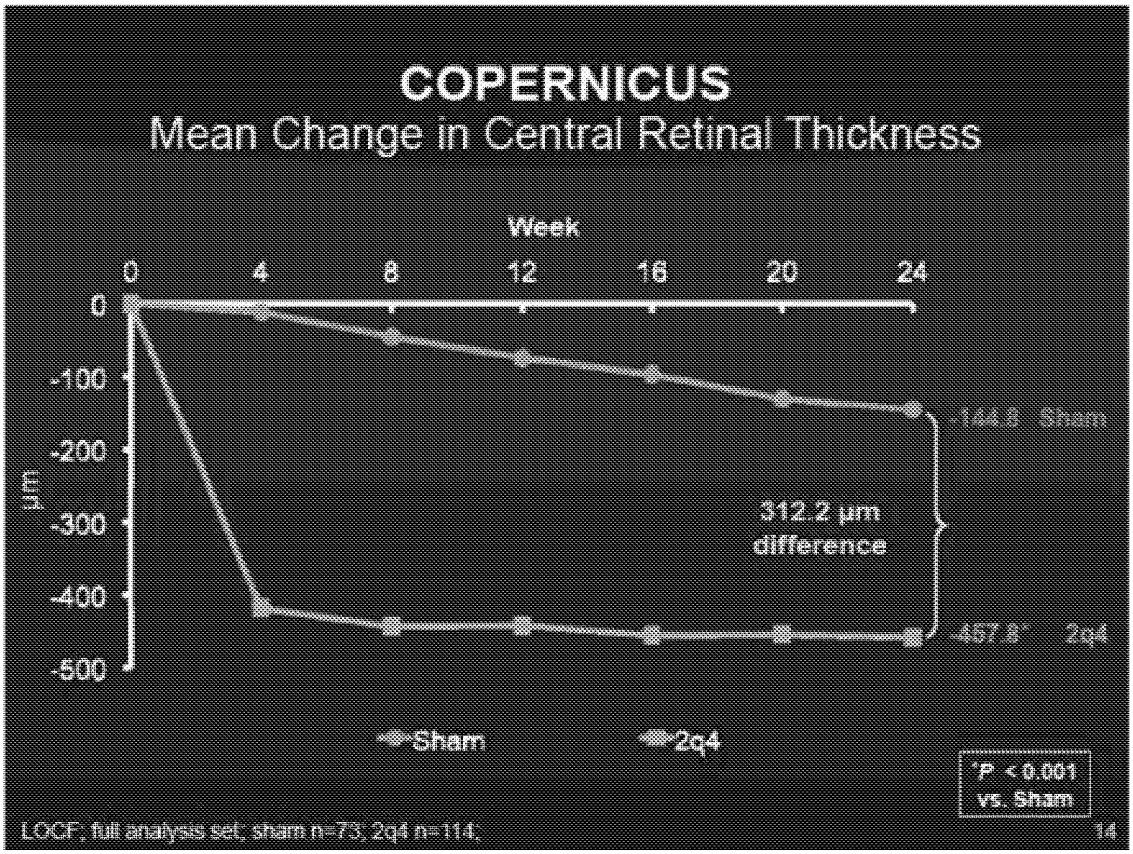

COPERNICUS
% Patients Who Gain ≥ 15 letters at Week 24
100%
80%
60%
40%
20%
0%
% Patients
12.3%
55.1%*
≥ 15 letter gain^
Sham
2q4
*P <0.0001 vs. Sham
^Compared to baseline, LOCF, full analysis set; sham n=73; 2q4 n=114;
9

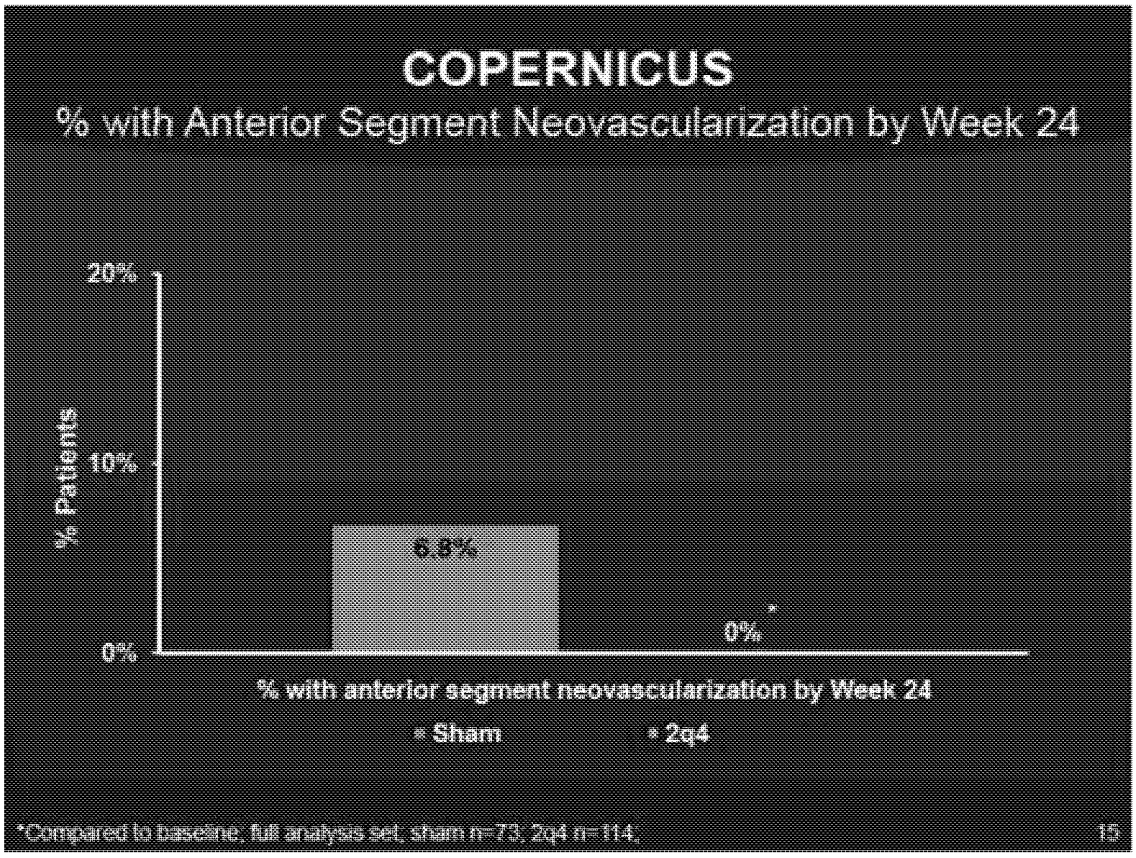

COPERNICUS
% Patients Who Gained ≥ 15 letters
70%
60%
50%
40%
30%
20%
10%
0%
% Patients
0
4
8
12
16
20
24
Week
Sham
2q4
56.1%* 2q4
43.8% difference
*P < 0.0001 vs. Sham
12.3% sham
*P < 0.0001 vs. sham
LOCF; full analysis set, sham n=73, 2q4 n=114;
10

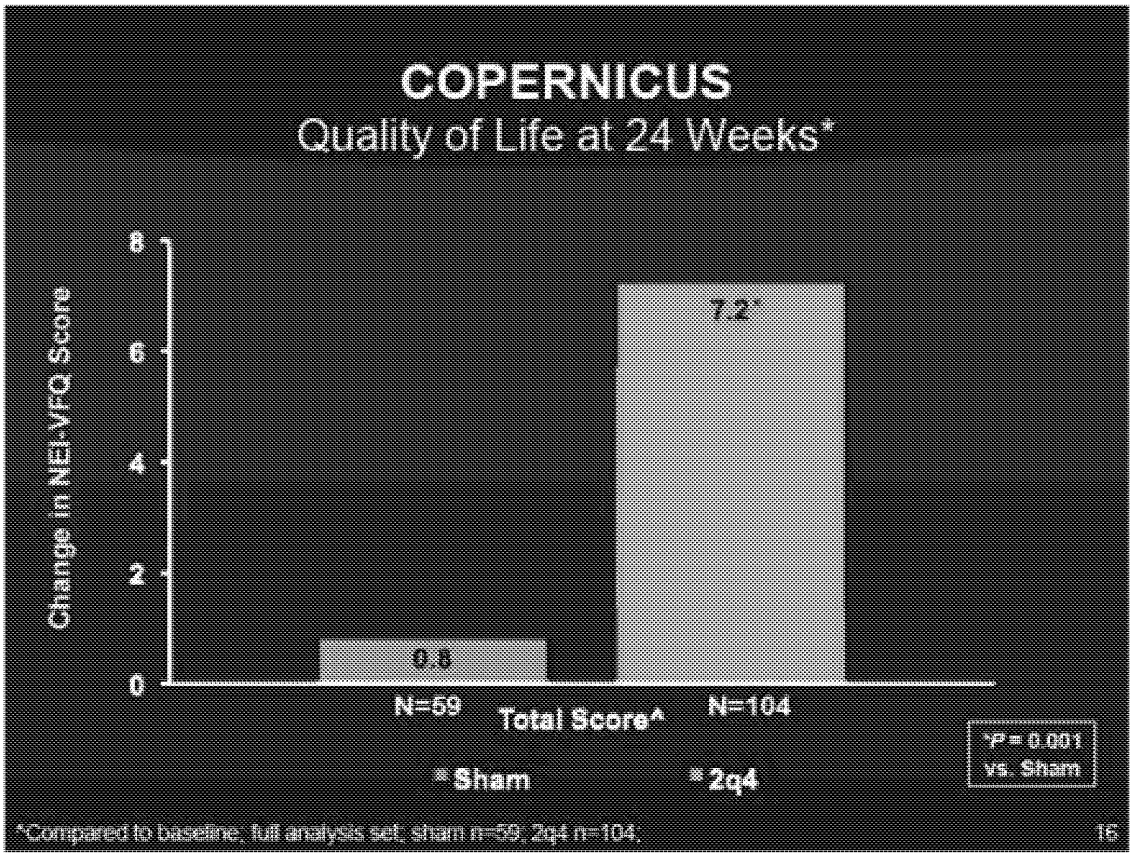

COPERNICUS
Mean Change in Visual Acuity
ETDRS letters
18
13
8
3
-2
-7
0
4
8
12
16
20
24
Week
+17.3 2q4
21.3 letter difference
*P < 0.001 vs. Sham
-4.0 Sham
Sham
2q4
LOCF; full analysis set; sham n=73, 2q4 n=114;
11

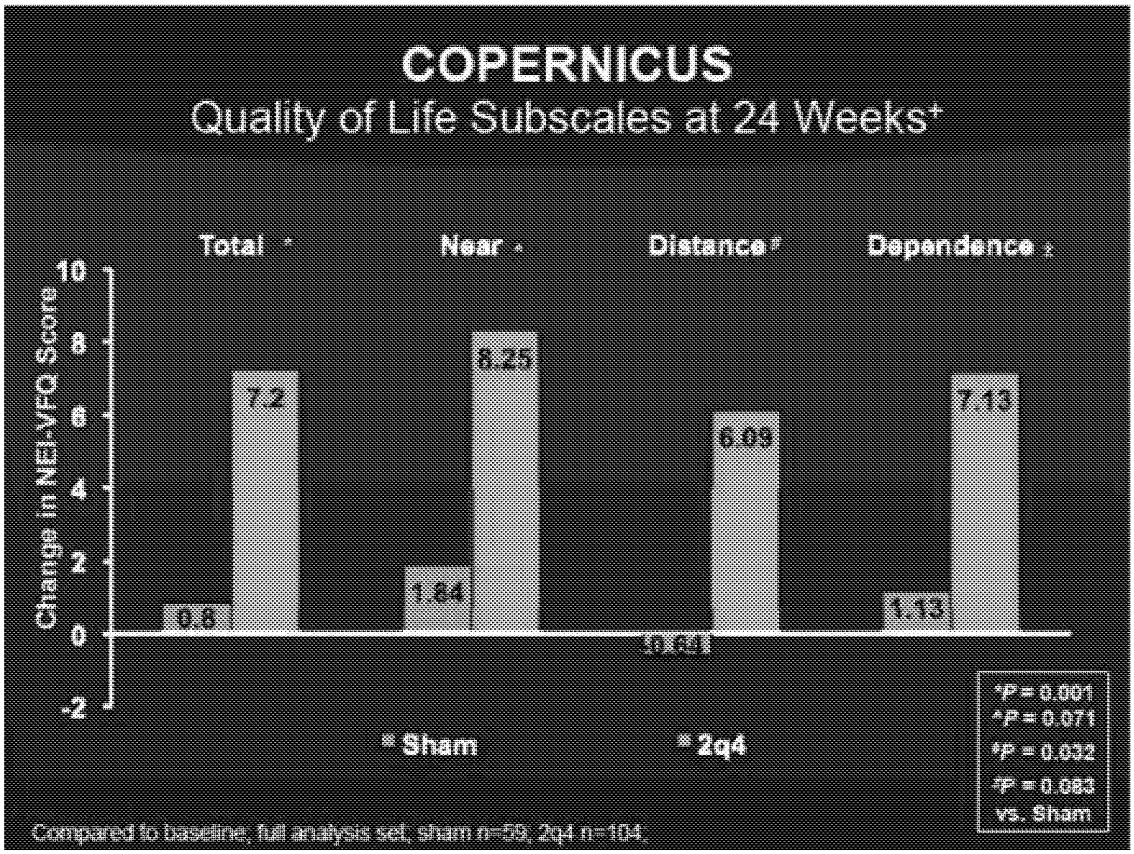

COPERNICUS
Proportion of Patients Who Gained Vision at Week 24*
100%
80%
60%
40%
20%
0%
% Patients
* Sham
* 2q4
51%
81%
22%
75%
12%
55%
0%
14%
≥ 0 letter gain*
≥ 10 letter gain*
≥ 15 letter gain*
≥ 30 letter gain*
*Compared to baseline; Full analysis set; sham n=73; 2q4 n=114;
12


COPERNICUS
Mean Change in Visual Acuity at Week 24
Sham
Change from Baseline
n=73
2q4
Change from Baseline
n=114


COPERNICUS
Mean Change in Central Retinal Thickness
Week
0
4
8
12
16
20
24
0
-100
-200
-300
-400
-500
µm
-144.8 Sham
312.2 µm difference
-457.8* 2q4
Sham
2q4
*P < 0.001 vs. Sham
LOCF; full analysis set; sham n=73; 2q4 n=114;
14


COPERNICUS
% with Anterior Segment Neovascularization by Week 24
20%
10%
0%
% Patients
6.8%
0%
*
% with anterior segment neovascularization by Week 24
Sham
2q4
*Compared to baseline; full analysis set; sham n=73, 2q4 n=114;
15


COPERNICUS
Quality of Life at 24 Weeks*
Change in NEI-VFQ Score
8
6
4
2
0
0.6
7.2*
N=59
Total Score^
N=104
Sham
2q4
*P = 0.001
vs. Sham
*Compared to baseline; full analysis set; sham n=59; 2q4 n=104;
16


COPERNICUS
Quality of Life Subscales at 24 Weeks+
Total *
Near ^
Distance #
Dependence ±
Change in NEI-VFQ Score
10
8
6
4
2
0
-2
0.8
7.2
1.84
8.25
6.09
1.13
7.13
Sham
2q4
*P = 0.001
^P = 0.071
#P = 0.032
±P = 0.083
vs. Sham
Compared to baseline; full analysis set; sham n=59, 2q4 n=104.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
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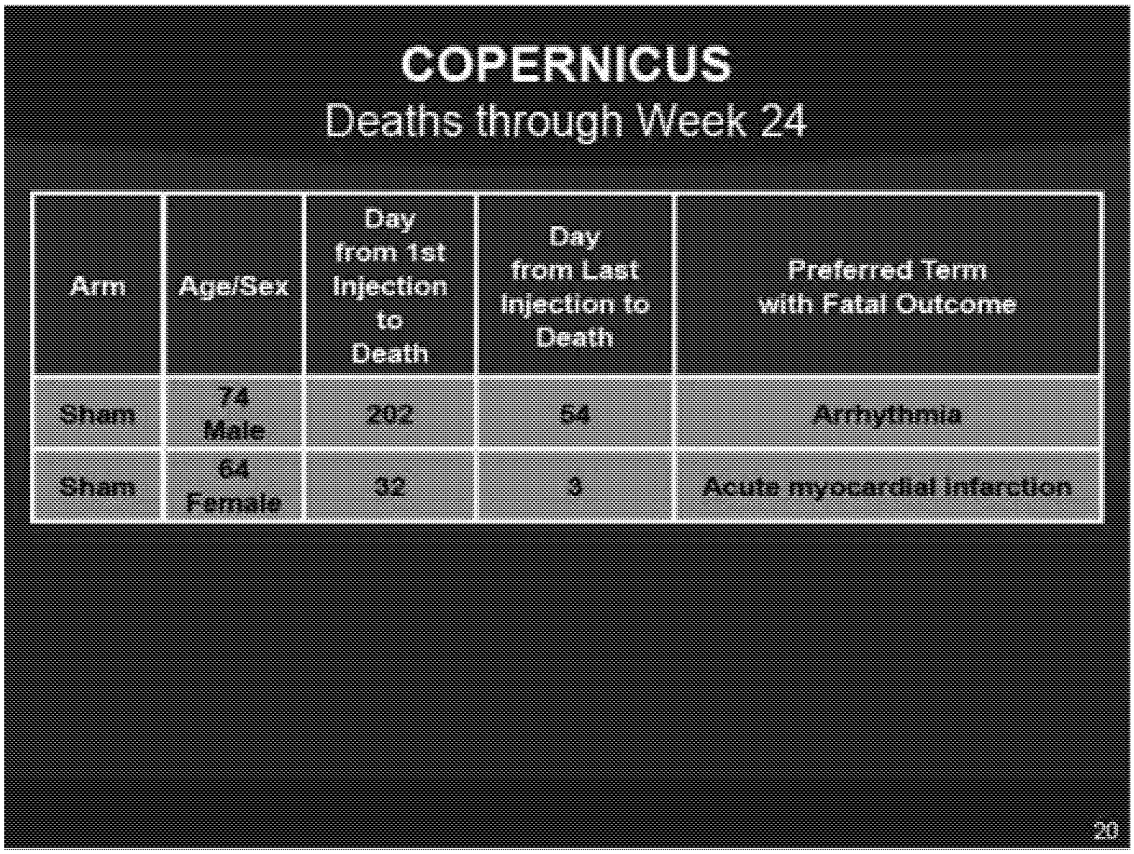
COPERNICUS

% Patients with Study Eye Ocular SAEs at Week 24

	Sham	VTE 2q4
n (safety analysis set)	74	114
# subjects with at least 1 AE	10 (13.5%)	4 (3.5%)
Vitreous Hemorrhage	4 (5.4%)	0
Neovascular Glaucoma	2 (2.7%)	0
Iris Neovascularization	2 (2.7%)	0
Retinal hemorrhage	2 (2.7%)	0
Visual acuity reduced	1 (1.4%)	1 (0.9%)
Retinal Artery Occlusion	0	1 (0.9%)
Retinal Tear	1 (1.4%)	0
Retinal Vein Occlusion	1 (1.4%)	0
Endophthalmitis	0	1 (0.9%)
Corneal Abrasion	0	1 (0.9%)

19

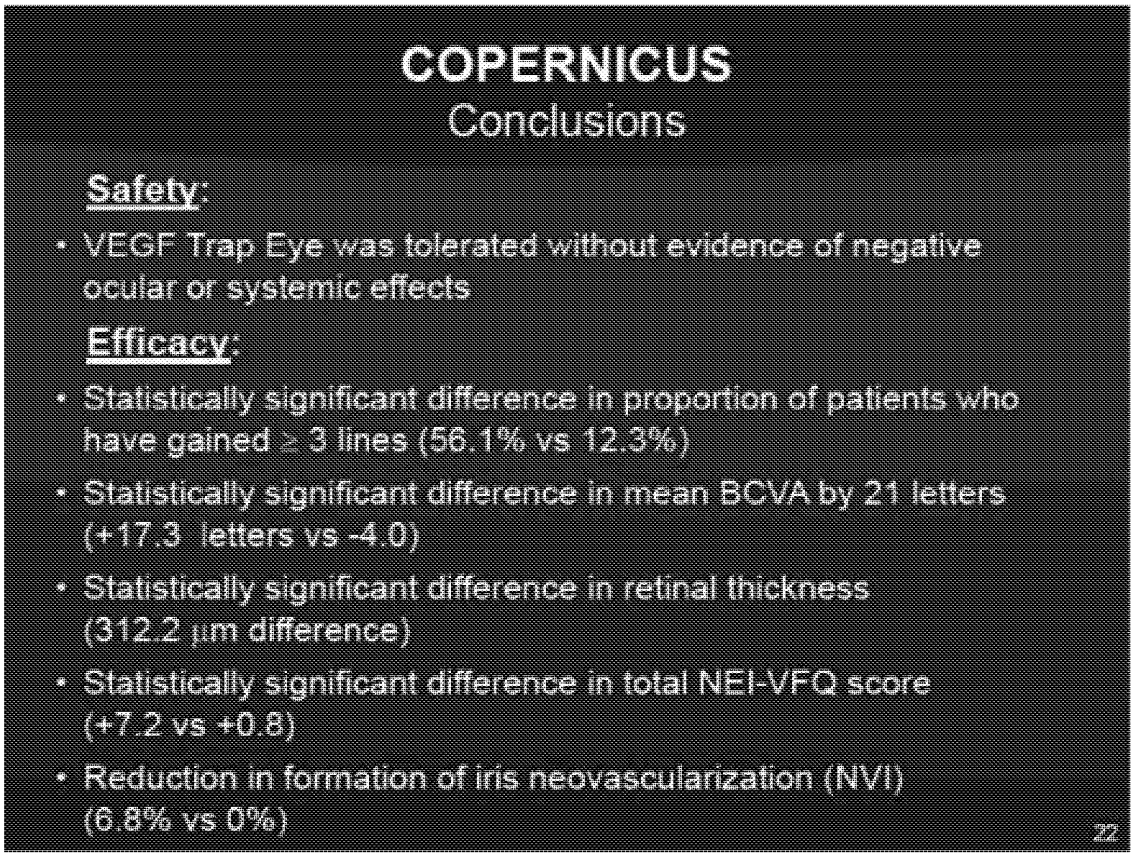

COPERNICUS
Deaths through Week 24
Arm
Age/Sex
Day from 1st Injection to Death
Day from Last Injection to Death
Preferred Term with Fatal Outcome
Sham
74 Male
202
54
Arrhythmia
Sham
64 Female
32
3
Acute myocardial infarction
20

COPERNICUS

% Patients with APTC Events through Week 24

	Sham	VTE 2q4
N (safety analysis set)	74	114
Total	2 (2.7%)	0
Vascular Deaths	2 (2.7%)	0
MI	1	0
Stroke	0	0
Arrhythmia	1	0
Non Fatal MI	0	0
Non Fatal Stroke (ischemic)	0	0

21


COPERNICUS
Conclusions
Safety:
• VEGF Trap Eye was tolerated without evidence of negative ocular or systemic effects
Efficacy:
• Statistically significant difference in proportion of patients who have gained ≥ 3 lines (56.1% vs 12.3%)
• Statistically significant difference in mean BCVA by 21 letters (+17.3 letters vs -4.0)
• Statistically significant difference in retinal thickness (312.2 μm difference)
• Statistically significant difference in total NEI-VFQ score (+7.2 vs +0.8)
• Reduction in formation of iris neovascularization (NVI) (6.8% vs 0%)
22

COPERNICUS
One Year Analysis

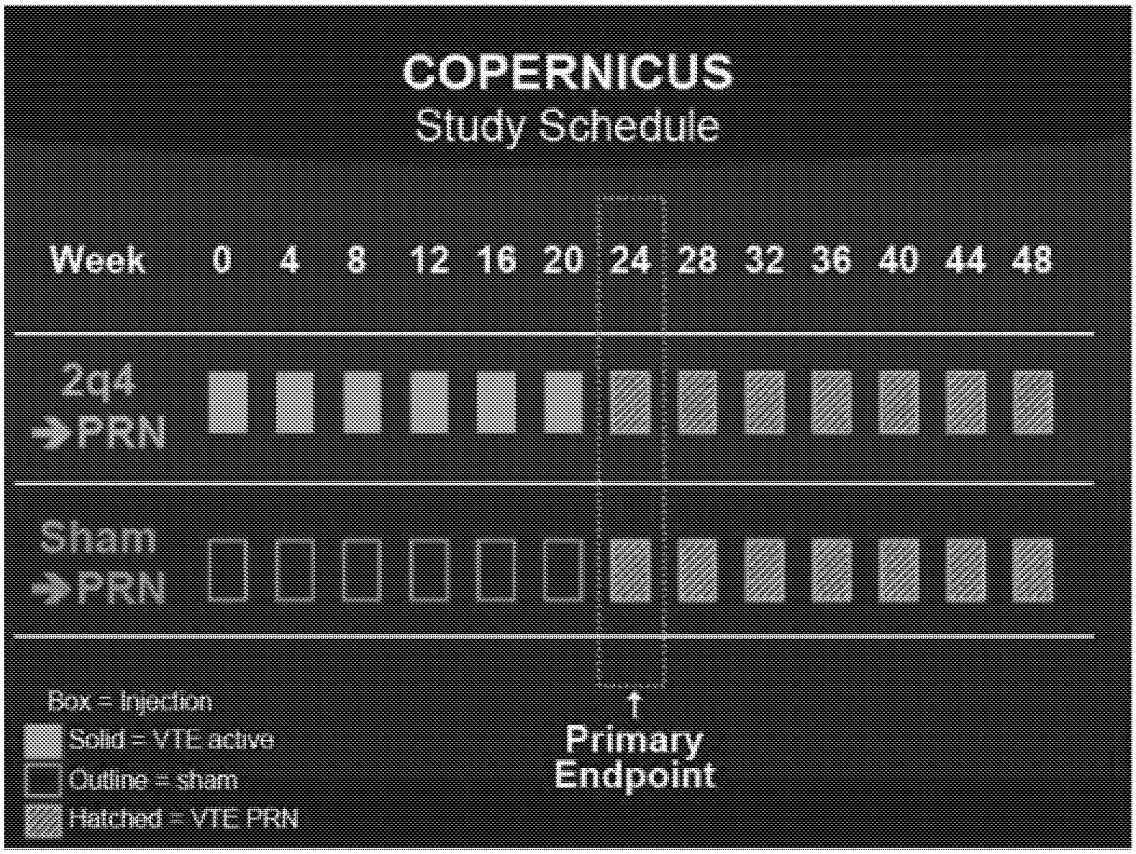
- After the primary endpoint at Week 24, all patients were eligible to receive VEGF Trap-Eye on a PRN basis

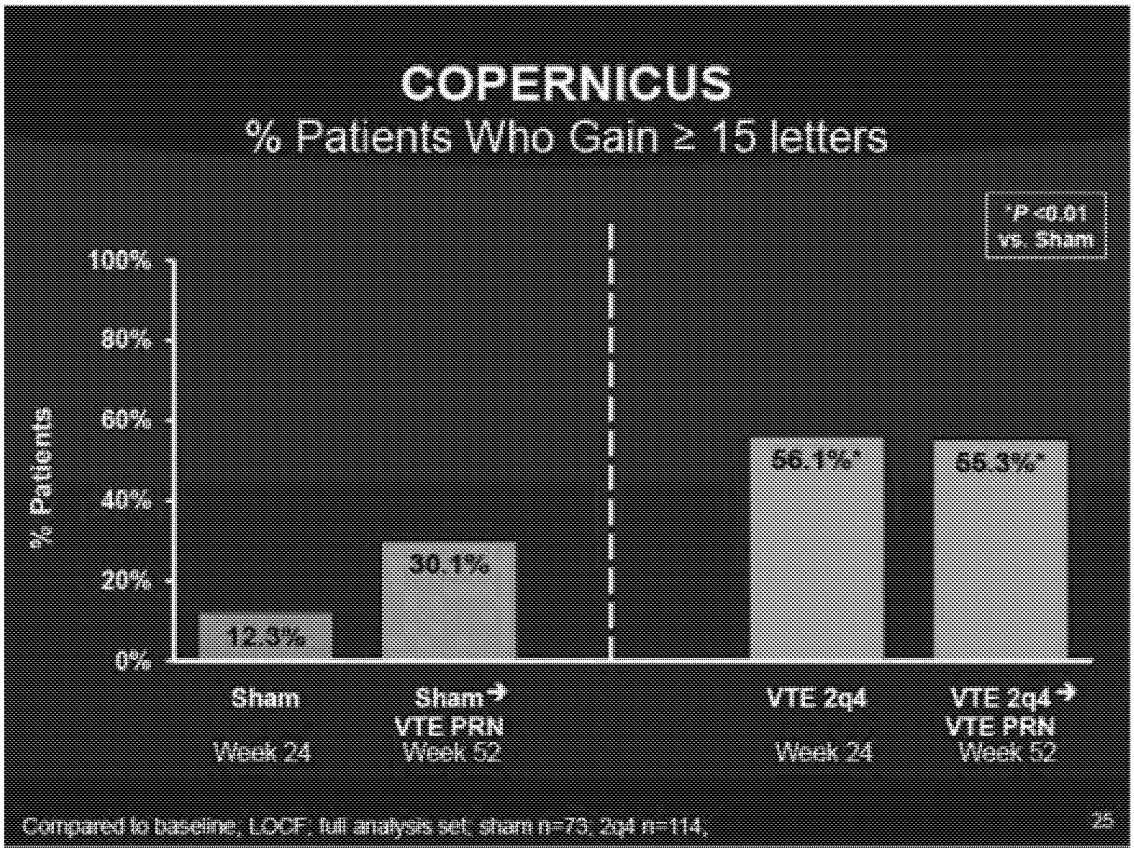
Sham → VTE PRN

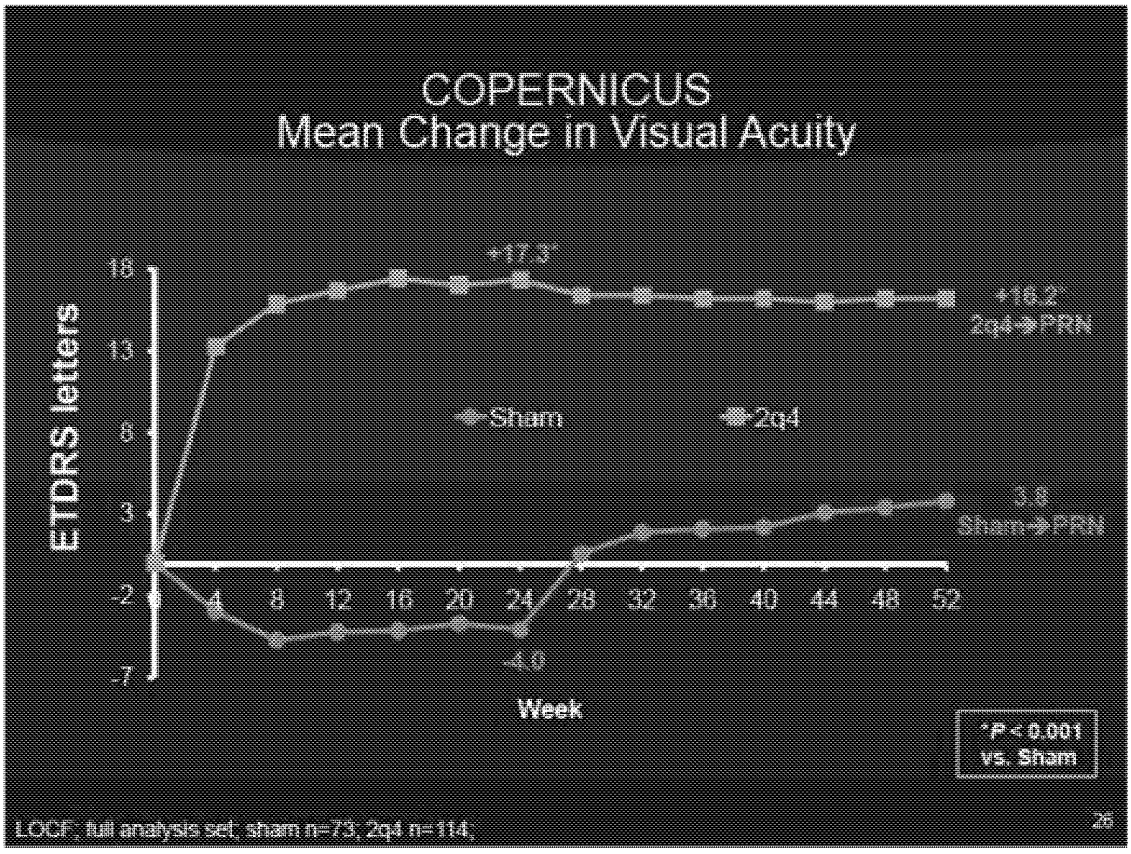
VTE 2q4 → VTE PRN

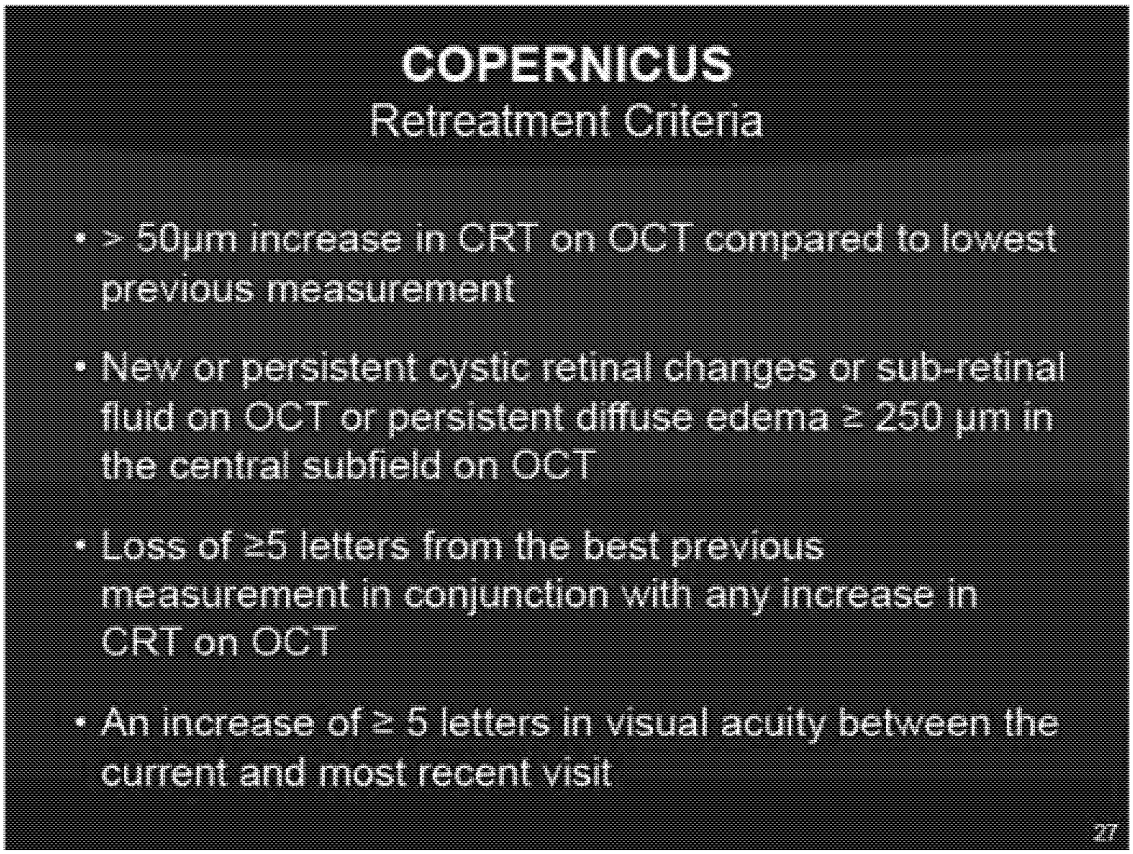
- Therefore, all but 3 patients in the sham arm who continued into the 2nd 6 months of the study received at least one dose of VEGF Trap-Eye

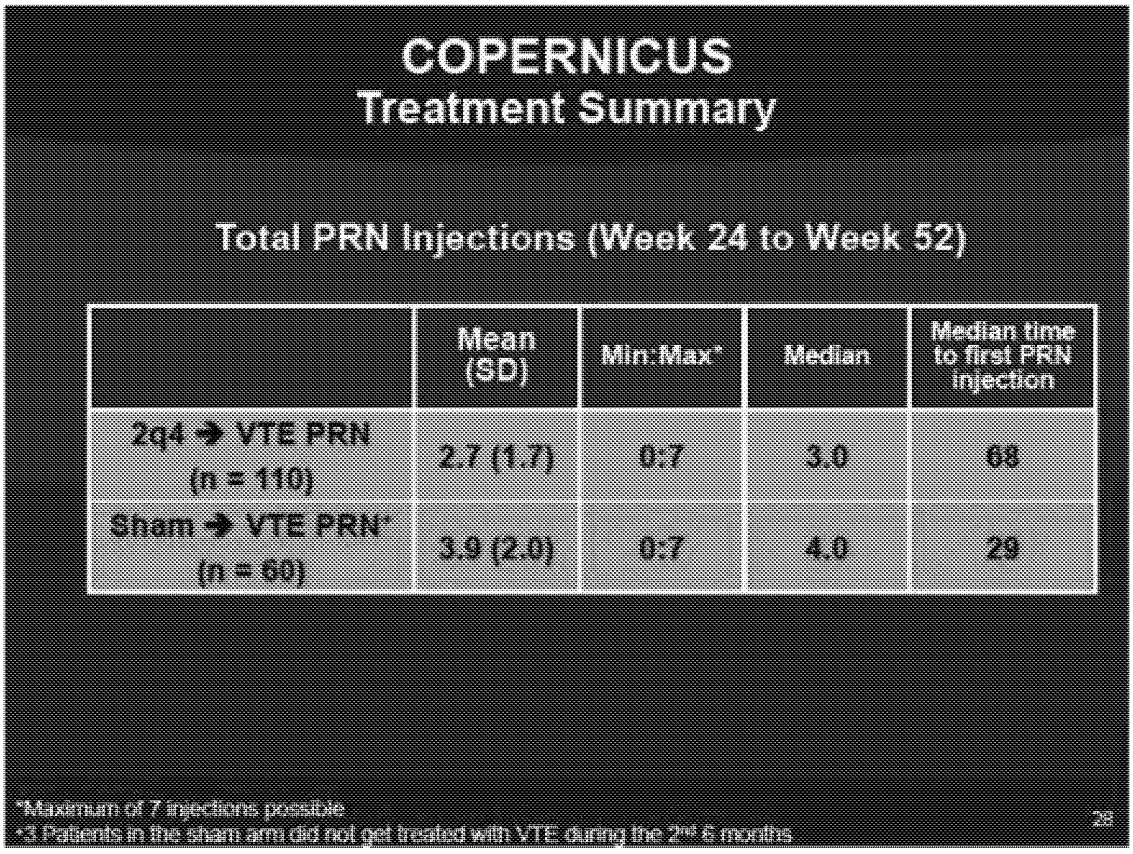
23


COPERNICUS
Study Schedule
Week 0 4 8 12 16 20 24 28 32 36 40 44 48
2q4
→PRN
Sham
→PRN
Box = Injection
Solid = VTE active
Outline = sham
Hatched = VTE PRN
Primary
Endpoint


COPERNICUS
% Patients Who Gain ≥ 15 letters
*P <0.01 vs. Sham
100%
80%
60%
40%
20%
0%
% Patients
12.3%
30.1%
56.1%*
55.3%*
Sham
Week 24
Sham → VTE PRN
Week 52
VTE 2q4
Week 24
VTE 2q4 → VTE PRN
Week 52
Compared to baseline, LOCF; full analysis set; sham n=73, 2q4 n=114.
25


COPERNICUS
Mean Change in Visual Acuity
ETDRS letters
18
13
8
3
-2
-7
+17.3*
+16.2*
2q4→PRN
Sham
2q4
3.8
Sham→PRN
-4.8
0
4
8
12
16
20
24
28
32
36
40
44
48
52
Week
*P < 0.001
vs. Sham
LOCF; full analysis set; sham n=73; 2q4 n=114;
26


COPERNICUS
Retreatment Criteria
• > 50µm increase in CRT on OCT compared to lowest previous measurement
• New or persistent cystic retinal changes or sub-retinal fluid on OCT or persistent diffuse edema ≥ 250 µm in the central subfield on OCT
• Loss of ≥5 letters from the best previous measurement in conjunction with any increase in CRT on OCT
• An increase of ≥ 5 letters in visual acuity between the current and most recent visit
27


COPERNICUS
Treatment Summary
Total PRN Injections (Week 24 to Week 52)
Mean (SD)
Min:Max*
Median
Median time to first PRN injection
2q4 → VTE PRN (n = 110)
2.7 (1.7)
0:7
3.0
68
Sham → VTE PRN* (n = 60)
3.9 (2.0)
0:7
4.0
29
*Maximum of 7 injections possible
•3 Patients in the sham arm did not get treated with VTE during the 2nd 6 months
28

COPERNICUS

% Patients with Study Eye Ocular SAEs

	Sham BL - Wk 24	Sham → VTE PRN Wk 24 - 52	VTE 2q4 BL - Wk 24	VTE 2q4 → VTE PRN Wk 24 - 52
n (safety analysis set)	74	60	114	110
# subjects w/ ≥ 1 AE	10 (13.5%)	2 (3.3%)	4 (3.5%)	3 (2.7%)
Cataract	0	1 (1.7%)	0	1 (0.9%)
Retinal Hemorrhage	2 (2.7%)	0	0	0
Visual Acuity Reduced	1 (1.4%)	0	1 (0.9%)	0
Vitreous haemorrhage	4 (5.4%)	1 (1.7%)	0	1 (0.9%)
Cystoid macular edema	0	0		1 (0.9%)
Glaucoma	2 (2.7%)	1 (1.7%)	0	0
Iris Neovascularization	2 (2.7%)	0	0	0
Retinal tear	1 (1.4%)	1 (1.7%)	0	0
Retinal vein occlusion	1 (1.4%)	0	0	1 (0.9%)
Retinal Artery occlusion	0	0	1 (0.9%)	0
Endophthalmitis	0	0	1 (0.9%)	0
Corneal Abrasion	0	0	1 (0.9%)	0

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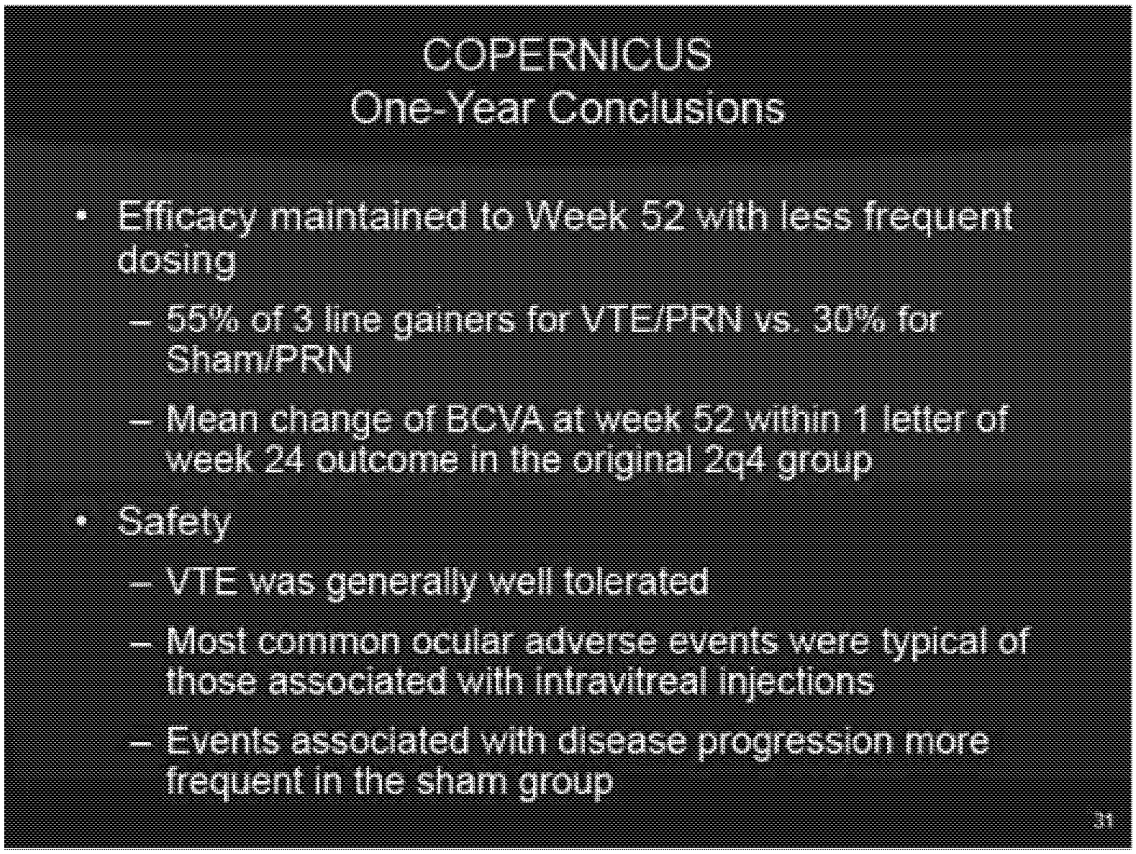
Samsung Bioepis Exhibit 1017, pg. 5160

COPERNICUS

% Patients with APTC Events

	Sham BL - Wk 24	Sham → VTE PRN Wk 24 - 52	VTE 2q4 BL - Wk 24	VTE 2q4 → VTE PRN Wk 24 - 52
N (safety analysis set)	74	60	114	110
Total	2 (2.7%)	0	0	1 (0.5%)
Vascular Deaths	2 (2.7%)	0	0	0
MI	1	0	0	0
Stroke	0	0	0	0
Arrhythmia	1	0	0	0
Non Fatal MI	0	0	0	1
Non Fatal Stroke (ischemic)	0	0	0	0

30


COPERNICUS
One-Year Conclusions
• Efficacy maintained to Week 52 with less frequent dosing
– 55% of 3 line gainers for VTE/PRN vs. 30% for Sham/PRN
– Mean change of BCVA at week 52 within 1 letter of week 24 outcome in the original 2q4 group
• Safety
– VTE was generally well tolerated
– Most common ocular adverse events were typical of those associated with intravitreal injections
– Events associated with disease progression more frequent in the sham group
31

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 11/21/2011

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 18, 2011 (November 18, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On November 18, 2011, Regeneron Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration approved EYLEA™ (aflibercept) Injection for the treatment of patients with neovascular (wet) Age-related Macular Degeneration (AMD).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release Announcing FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration, dated November 18, 2011.

SIGNATURES

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 hereunto duly authorized.

Date: November 18, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa
Name:Joseph J. LaRosa
Title:Senior Vice President, General Counsel and Secretary

Exhibit Index

Number	Description
99.1	Press Release Announcing FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration, dated November 18, 2011

Exhibit 99.1

REGENERON

For Immediate Release

Press Release

Regeneron Announces FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration

EYLEA is the only FDA-approved treatment for wet AMD labeled for less than monthly dosing that demonstrated clinical equivalence to the monthly standard of care

Regeneron to host conference call on November 18, at 6:30 p.m. Eastern Time

Tarrytown, NY (November 18, 2011) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced that the U.S. Food and Drug Administration (FDA) has approved EYLEA (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, for the treatment of patients with neovascular (wet) Age-related Macular Degeneration (AMD) at a recommended dose of 2 milligrams (mg) every four weeks (monthly) for the first 12 weeks, followed by 2 mg every eight weeks (2 months).

The approval of EYLEA was granted under a Priority Review, a designation that is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. This approval was based upon the results of two Phase 3 clinical studies. In these studies, EYLEA dosed every eight weeks, following three initial monthly injections, was clinically equivalent to the standard of care, Lucentis® (ranibizumab injection) dosed every four weeks, as measured by the primary endpoint of maintenance of visual acuity (less than 15 letters of vision loss on an eye chart) over 52 weeks. The most common adverse reactions (frequency of 5% or more) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure. The adverse event profile was similar to that seen with ranibizumab.

"The approval of EYLEA offers a much needed new treatment option for patients with wet AMD," said Jeffrey Heier, M.D., a clinical ophthalmologist and retinal specialist at Ophthalmic Consultants of Boston, Assistant Professor of Ophthalmology at Tufts School of Medicine, and Chair of the Steering Committee for the VIEW 1 trial. "EYLEA offers the potential of achieving the efficacy we've come to expect from current anti-VEGF agents, but with less frequent injections and no monitoring requirements. This may reduce the need for costly and time-consuming monthly office visits for patients and their caregivers."

"This approval is an important step forward for Regeneron and for patients suffering with wet AMD, the most common cause of blindness in the U.S. in older adults," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We thank the patients and clinical investigators who participated in our clinical studies, the FDA, and the Regeneron employees who helped make this day possible. Now that EYLEA is approved, we plan to make EYLEA available to patients within the next few days."

About EYLEA™ (aflibercept) Injection
Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as wet age-related macular degeneration, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results.

EYLEA, known in the scientific literature as VEGF Trap-Eye, is a recombinant fusion protein, consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. EYLEA acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of these cognate VEGF receptors.

EYLEA is indicated for the treatment of patients with neovascular age-related macular degeneration (wet AMD). EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

The recommended dose for EYLEA is 2 mg administered by intravitreal injection every four weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every eight weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every four weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every four weeks compared to every eight weeks.

There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs with EYLEA in clinical trials was low (1.8%) .

Serious adverse reactions related to the injection procedure have occurred in less than 0.1% of intravitreal injections with EYLEA and include endophthalmitis, traumatic cataract, and increased intraocular pressure.

About the VIEW 1 and VIEW 2 Clinical Studies

The safety and efficacy of EYLEA were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with EYLEA) in the two studies (VIEW 1 and VIEW 2). In each study, patients were randomly assigned in a 1:1:1:1 ratio to one of four dosing regimens: 1) EYLEA administered 2 mg every eight weeks following three initial monthly doses (EYLEA 2Q8); 2) EYLEA administered 2 mg every four weeks (EYLEA 2Q4); 3) EYLEA 0.5 mg administered every four weeks (EYLEA 0.5Q4); and 4) ranibizumab administered 0.5 mg every four weeks (ranibizumab 0.5Q4) . Patient ages ranged from 49 to 99 years with a mean of 76 years.

In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Data are available through week 52. Both the EYLEA™ (aflibercept) Injection 2Q8 and 2Q4 dosing groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5Q4 group for the primary endpoint.

Select results of the VIEW 1 and VIEW 2 studies as described in the full Prescribing

Information for the EYLEA 2 mg every four weeks and EYLEA 2 mg every eight weeks dosing groups as compared to ranibizumab dosed monthly group are shown below.

Efficacy Outcomes at Week 52 (Full Analysis Set with LOCF) in VIEW 1 and VIEW 2 Studies

	VIEW 1			VIEW 2		
	EYLEA 2 mg Q8 weeks[a]	EYLEA 2 mg Q4 weeks	ranibizumab 0.5 mg Q4 weeks	EYLEA 2 mg Q8 weeks[a]	EYLEA 2 mg Q4 weeks	ranibizumab 0.5 mg Q4 weeks
Full Analysis Set	N=301	N=304	N=304	N=306	N=309	N=291
Efficacy Outcomes						
Proportion of patients who maintained visual acuity (%) (<15 letters of BCVA loss)	94%	95%	94%	95%	95%	95%
Difference[b] (%) (95.1% CI)	0.6 (-3.2, 4.4)	1.3 (-2.4, 5.0)		0.6 (-2.9, 4.0)	-0.3 (-4.0, 3.3)	
Mean change in BCVA as measured by ETDRS letter score from Baseline	7.9	10.9	8.1	8.9	7.6	9.4
Difference[b] in LS mean (95.1% CI)	0.3 (-2.0, 2.5)	3.2 (0.9, 5.4)		-0.9 (-3.1, 1.3)	-2.0 (-4.1, 0.2)	

BCVA = Best Corrected Visual Acuity; CI = Confidence Interval; ETDRS = Early Treatment Diabetic Retinopathy Study; LOCF = Last Observation Carried Forward (baseline values are not carried forward); 95.1% confidence intervals were presented to adjust for safety assessment conducted during the study.

[a] After treatment initiation with 3 monthly doses

[b] EYLEA group minus the ranibizumab group

IMPORTANT SAFETY INFORMATION

EYLEA™ (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.

Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs with EYLEA in clinical trials was low (1.8%) .

Serious adverse reactions related to the injection procedure have occurred in less than 0.1% of intravitreal injections with EYLEA including endophthalmitis, traumatic cataract, and increased intraocular pressure.

The most common adverse reactions (greater than or equal to 5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.

Please see the full Prescribing Information for EYLEA, available online at www.regeneron.com/EYLEA-fpi.pdf.

About the EYLEA™ (aflibercept) Injection Global Collaboration
Regeneron is collaborating with Bayer HealthCare on the global development of EYLEA. Bayer submitted an application for marketing authorization in Europe for wet AMD in June 2011.

Bayer HealthCare will market EYLEA outside the United States, where the companies will share equally the profits from any future sales of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States.

About Wet AMD
Age-related macular degeneration (AMD) is a leading cause of acquired blindness. Macular degeneration is diagnosed as either dry (non-exudative) or wet (exudative). In wet AMD, new blood vessels grow beneath the retina and leak blood and fluid. This leakage causes disruption and dysfunction of the retina creating distortion and/or blind spots in central vision. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

Conference Call Information
Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron, and other members of senior management will host a conference call to discuss the FDA approval of EYLEA for the treatment of patients with wet AMD and launch plans, as well as other corporate matters. The interactive call will be held on November 18, 2011 at 6:30 p.m. Eastern Time and can be accessed live through the Regeneron website at www.regeneron.com on the Investor Relations page. The call, including the question and answer session, can also be accessed by dialing:

Domestic Dial-in Number: (888) 660-6127

International Dial-in Number: (973) 890-8355

Participant Passcode: 30193445

An archived version of the conference call will be available for 30 days on the company's website at www.regeneron.com on the Investor Relations page.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets two products, ARCALYST® (rilonacept) Injection For Subcutaneous Use and EYLEA™ (aflibercept) Injection. Regeneron also has completed several Phase 3 studies and is conducting an additional Phase 3 clinical trial for the product candidate ZALTRAP® (aflibercept) Concentrate for Intravenous Infusion. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on the Regeneron web site at www.regeneron.com.

Regeneron Forward Looking Statement
This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of EYLEA and Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize EYLEA and other products and drug candidates, competing drugs that may be superior to EYLEA and Regeneron's products and drug candidates, uncertainty of market acceptance of EYLEA and Regeneron's products and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2010 and Form 10-Q for the quarter ended September 30, 2011. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

###

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STACK:

/quit
-dictionary-
-mark-
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Page 5177

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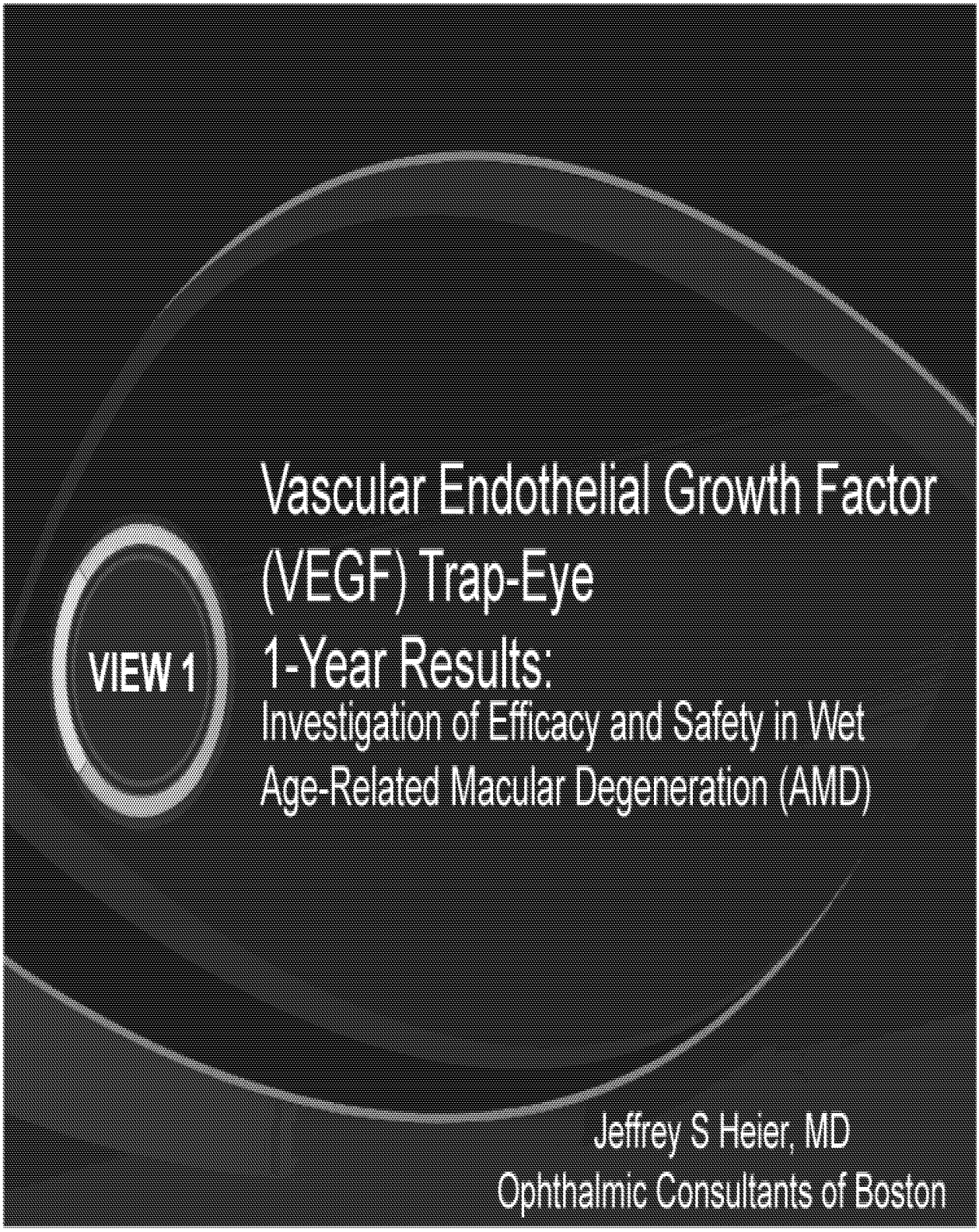

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Financial Disclosure

- Scientific Advisor:

  Alcon, Genentech, Genzyme, GlaxoSmithKline, LPath, Neovista, Oraya, Paloma, Regeneron, Sequenom

- Research Support:

  Alcon, Genentech, Genzyme, GlaxoSmithKline, Neovista, Ophthotech, Regeneron

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Introduction

- Anti-VEGF therapy has led to dramatic advances in the treatment of exudative AMD
  - The large majority of patients are stabilized
  - Significant visual gain in **25-40%**
- Such outcomes appear to be dependent upon frequent injections over prolonged periods
  - Attempts at reducing the treatment burden often lead to less robust outcomes

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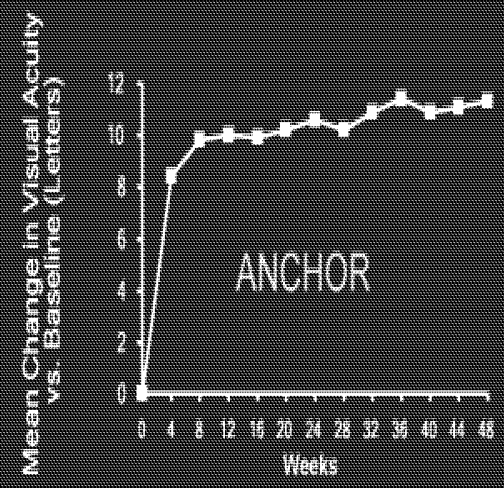
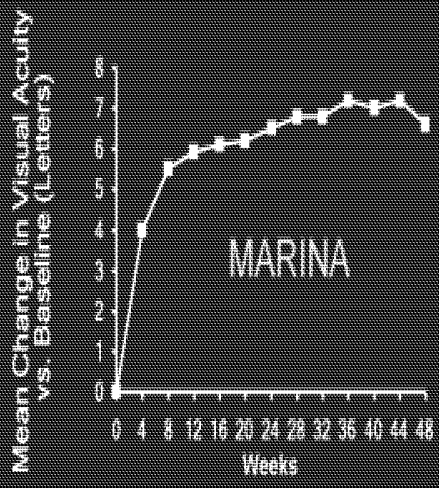
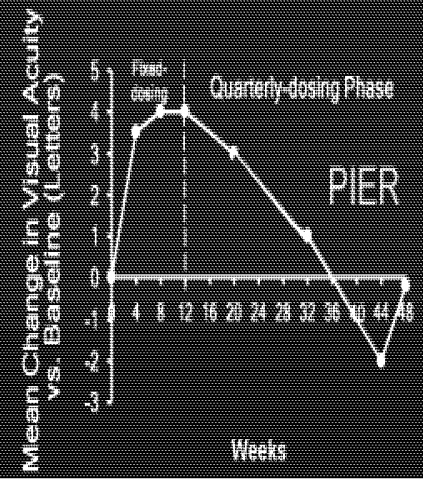
The Dilemma With Anti-VEGF Treatment

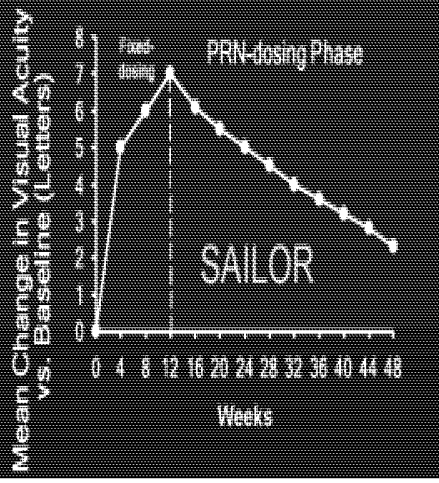
Vision gains maintained with monthly dosing





Vision gains appear to diminish with less frequent dosing





4

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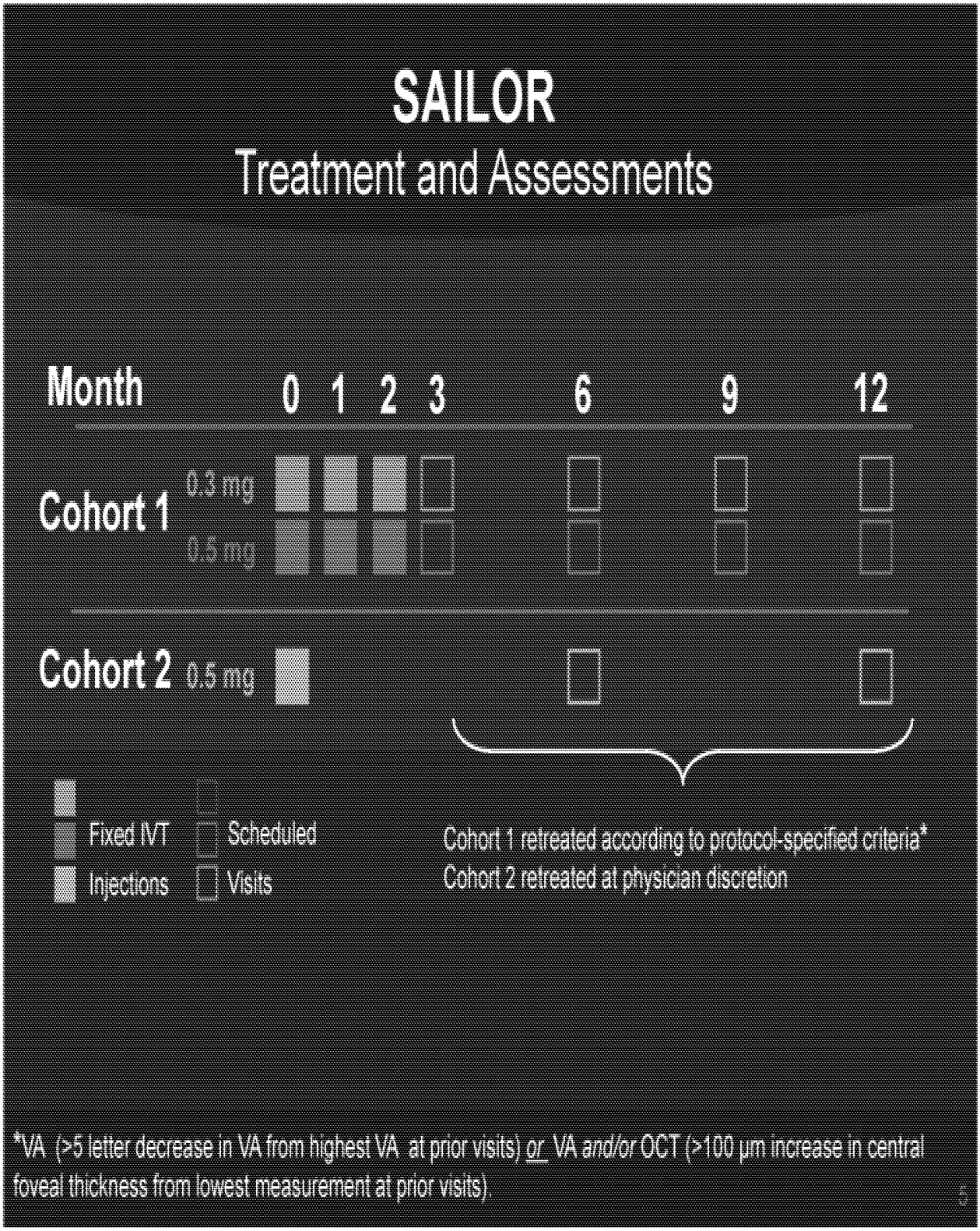
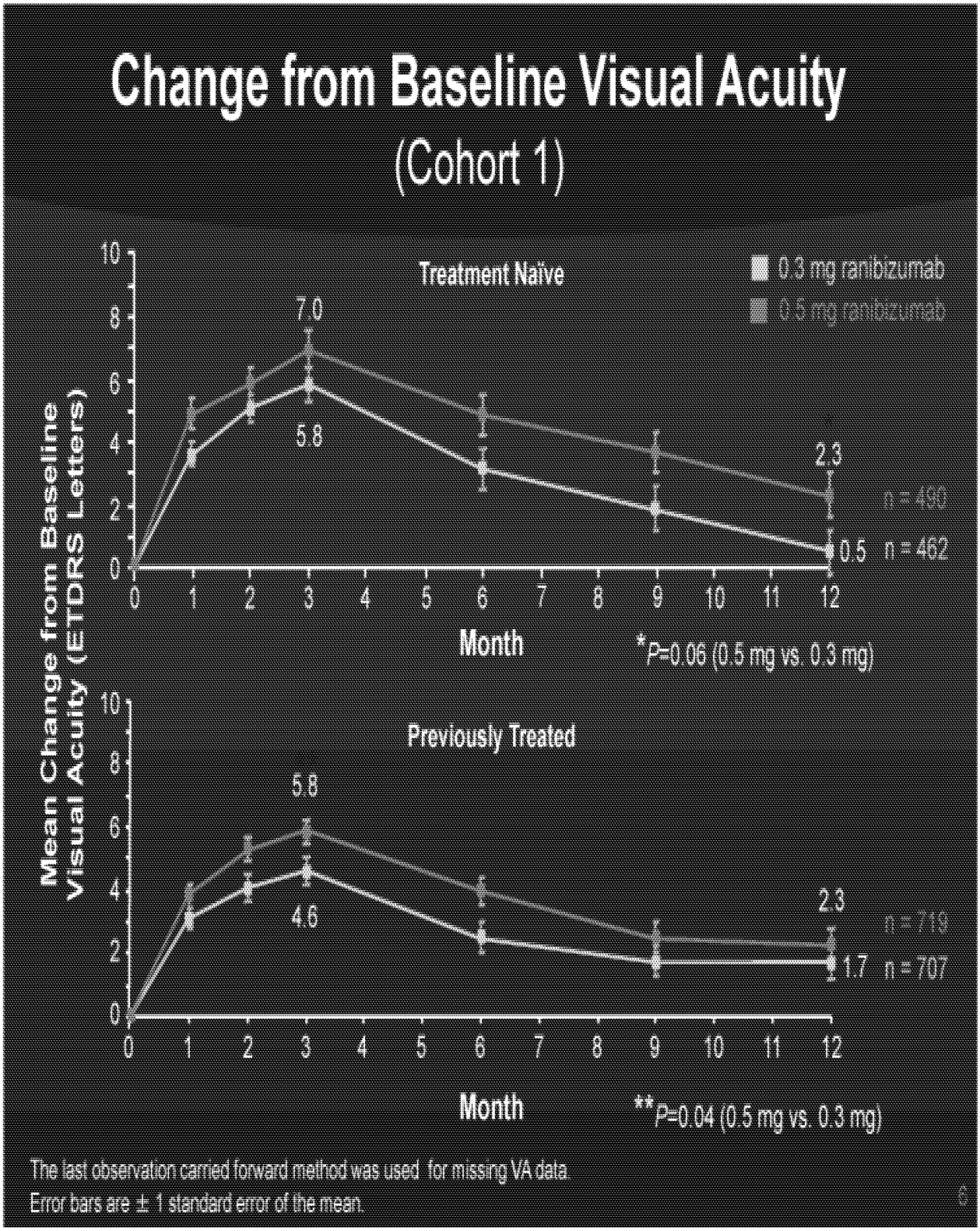
SAILOR
Treatment and Assessments



*VA (>5 letter decrease in VA from highest VA at prior visits) *or* VA *and/or* OCT (>100 µm increase in central foveal thickness from lowest measurement at prior visits).


Change from Baseline Visual Acuity
(Cohort 1)
Mean Change from Baseline Visual Acuity (ETDRS Letters)
Treatment Naïve
0.3 mg ranibizumab
0.5 mg ranibizumab
7.0
5.8
2.3
n = 490
0.5
n = 462
Month
*P=0.06 (0.5 mg vs. 0.3 mg)
Previously Treated
5.8
4.6
2.3
n = 719
1.7
n = 707
Month
**P=0.04 (0.5 mg vs. 0.3 mg)
The last observation carried forward method was used for missing VA data.
Error bars are ± 1 standard error of the mean.

Not a New Concept

Year 2 Efficacy Results of 2 Randomized Controlled Clinical Trials of Pegaptanib for Neovascular Age-Related Macular Degeneration

VEGF Inhibition Study in Ocular Neovascularization (V.I.S.I.O.N.) Clinical Trial Group*

Objective: To evaluate the efficacy of a second year of pegaptanib sodium therapy in patients with neovascular age-related macular degeneration (AMD).

Design: Two concurrent, multicenter, randomized, dose-masked, sham-controlled studies (V.I.S.I.O.N. [Vascular Endothelial Growth Factor Inhibition Study in Ocular Neovascularization] trials).

Participants: Patients with all angiographic neovascular lesion compositions of AMD were enrolled. In combined analysis, 88% (1003/1186) were re-randomized at week 54, and 86% (841/1000) were assessed at week 102.

Interventions: At week 54, those initially assigned to pegaptanib were re-randomized 1:1:1 to continue or discontinue therapy for 48 more weeks (3 injections). Those initially assigned to sham were re-randomized to continue sham, discontinue sham, or receive 1 of 3 pegaptanib doses.

Main Outcome Measures: Mean change in visual acuity (VA) over time and mean change in the standardized area under the curve of VA and proportions of patients experiencing a loss of <15 letters from week 54 to week 102; losing <15 letters prospectively from baseline to week 102; gaining ≥15, ≥10, and ≥5 letters at week 102; and experiencing no legal blindness (20/200 or worse).

Results: In combined analysis, mean VA was maintained in patients continuing with 0.3-mg pegaptanib compared with those discontinuing therapy or receiving usual care. In patients who continued pegaptanib, the proportion who lost >15 letters from baseline in the period from week 54 to week 102 was 22% that of patients who discontinued pegaptanib or remained on usual care (7.4% for each). Kaplan–Meier analyses indicated that patients continuing 0.3-mg pegaptanib for a second year were less likely to lose >15 letters than those re-randomized to discontinue after 1 year ($P < 0.05$). The proportion of patients gaining vision was higher for those assigned to 2 years of 0.3-mg pegaptanib than receiving usual care. Progressively less treatment was indicated for patients continuing 0.3-mg pegaptanib for 2 years.

Conclusions: Continuing visual benefit was observed in patients who were randomized to receive therapy with pegaptanib in year 2 of the V.I.S.I.O.N. trials when compared with 2 years' usual care or cessation of therapy at year 1. Ophthalmology 2006;113:1508–1521 © 2006 by the American Academy of Ophthalmology.

From a worldwide perspective, age-related macular degeneration (AMD) has been estimated to cause 8.7% of total blindness.[1] In the United Kingdom, 2.5% of individuals >75 years of age were legally registered blind to AMD;[2] it has been estimated that in the United States as many as 15 million people suffer from some form of AMD,[3] with more than 1.6 million experiencing the active blood vessel growth and leakage associated with neovascular AMD.[4] Many studies have shown that both eyes of eyes with this disorder have experienced moderate or severe vision loss within 5 years of presentation.[5–7]

The presence of vascular endothelial growth factor (VEGF), particularly the $VEGF_{165}$ isoform, has been implicated as a key predictor in the pathogenesis of blood vessel growth and leakage, both hallmarks of neovascular AMD. A prominent growth factor, VEGF stimulates blood vessel growth by promoting endothelial cell proliferation and survival,[8,9] inhibiting bone marrow–derived endothelial cell precursors,[10,11] upregulating the synthesis of enzymes that degrade the extracellular matrix, and increasing blood vessel permeability.[12,13] Vascular endothelial growth factor

Originally received: November 10, 2005.
Accepted: February 21, 2006.

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*Members of the study group providing substantial contributions to the overall study and who had complete access to the data reported in the report are listed in Appendix F, along with their personal financial conflict-of-interest statements.

1550-5413/$ – see front matter © 2006 by the American Academy of Ophthalmology
Published by Elsevier Inc.

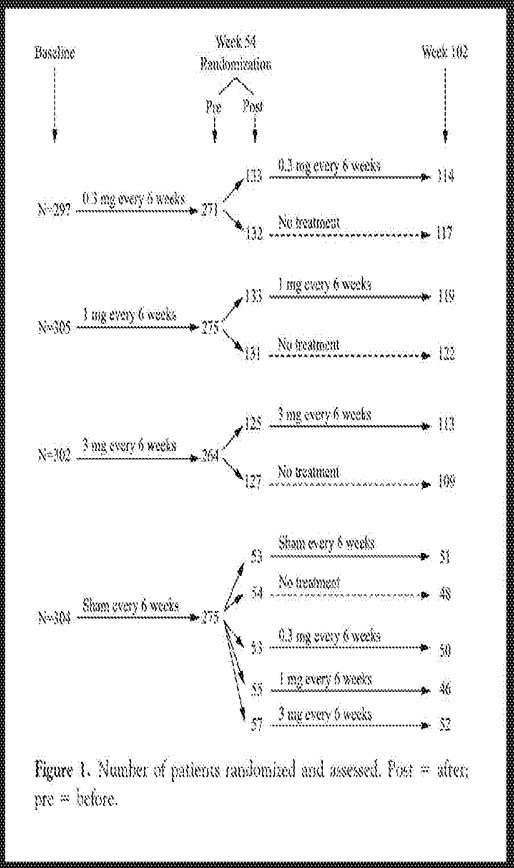

Figure 1. Number of patients randomized and assessed. Post = after; pre = before.

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Benefit of Continued Treatment

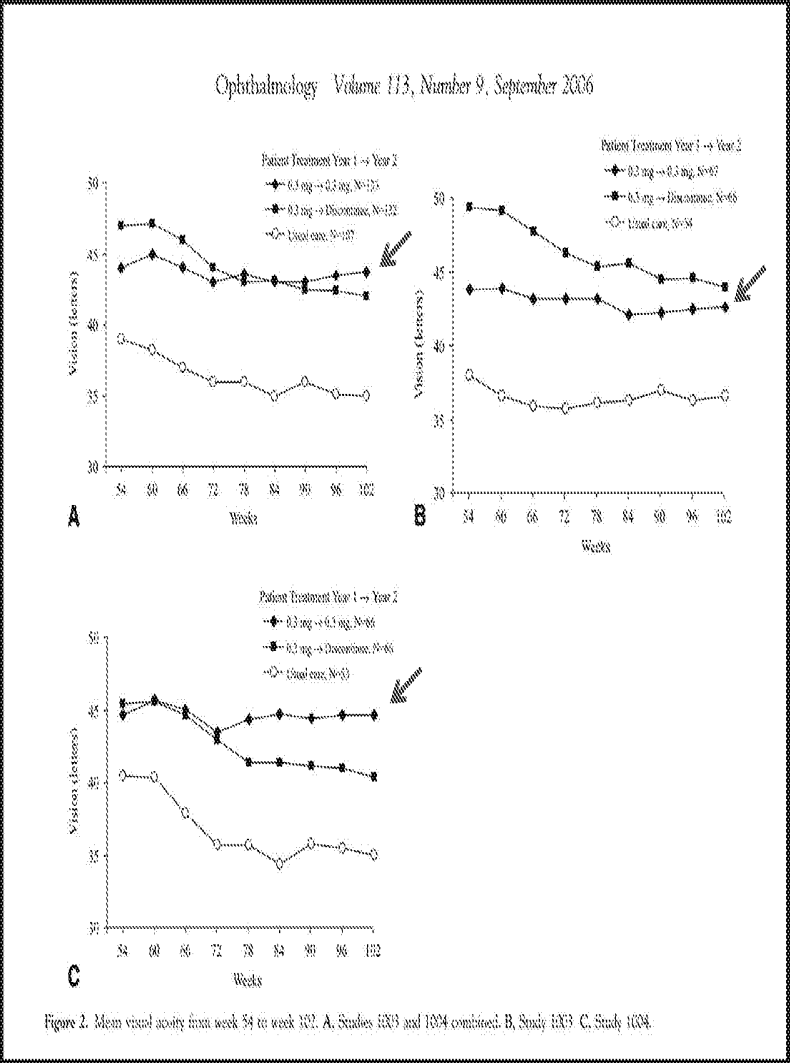
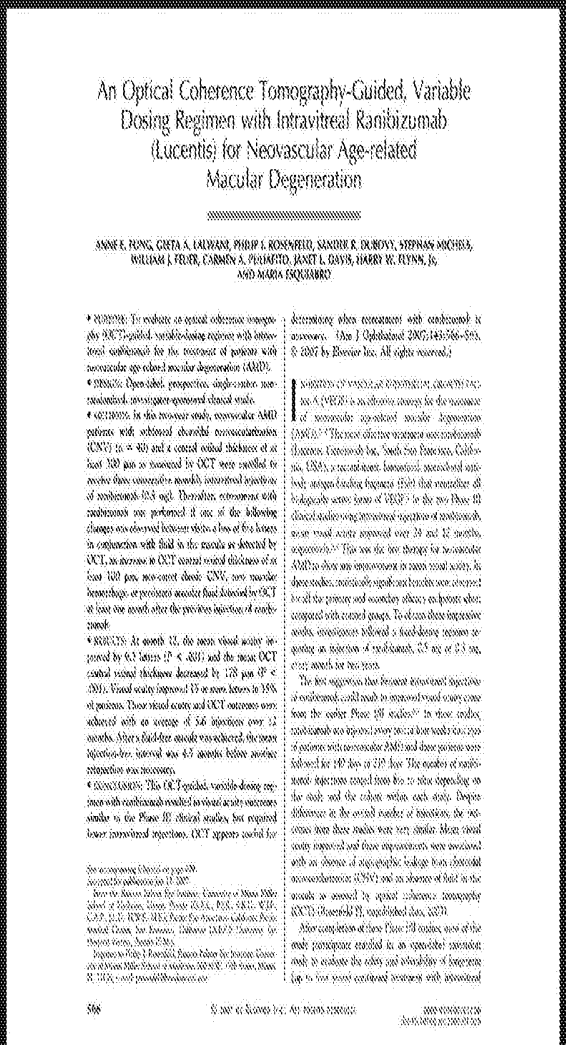


Figure 2. Mean visual acuity from week 54 to week 102. A, Studies 1033 and 1034 combined. B, Study 1033. C, Study 1034.

"The V.I.S.I.O.N. trials showed that 2 years' continued VEGF165 inhibition with pegaptanib provided patients with the best chance of preserving vision"

Can Variable Dosing Lead to Significant Visual Gain?

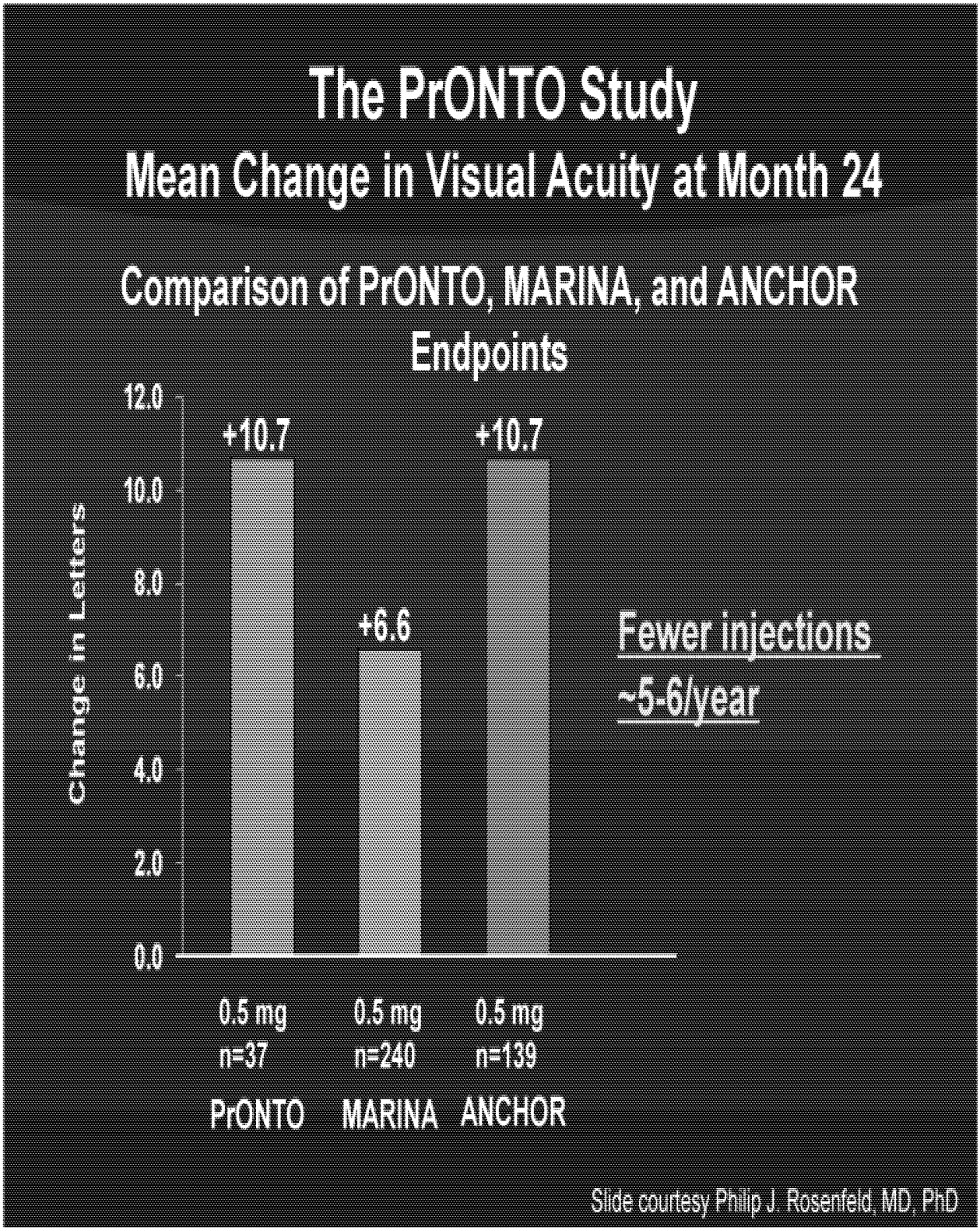


An Optical Coherence Tomography-Guided, Variable Dosing Regimen with Intravitreal Ranibizumab (Lucentis) for Neovascular Age-related Macular Degeneration

ANNE E. FUNG, GRETA A. LALWANI, PHILIP J. ROSENFELD, SANDRA R. DUBOVY, STEPHAN MICHELS, WILLIAM J. FEUER, CARMEN A. PULIAFITO, JANET L. DAVIS, HARRY W. FLYNN, JR, AND MARIA ESQUIABRO

A Variable-dosing Regimen with Intravitreal Ranibizumab for Neovascular Age-related Macular Degeneration: Year 2 of the PrONTO Study

GRETA A. LALWANI, PHILIP J. ROSENFELD, ANNE E. FUNG, SANDRA R. DUBOVY, STEPHEN MICHELS, WILLIAM FEUER, JANET L. DAVIS, HARRY W. FLYNN, JR, AND MARIA ESQUIABRO



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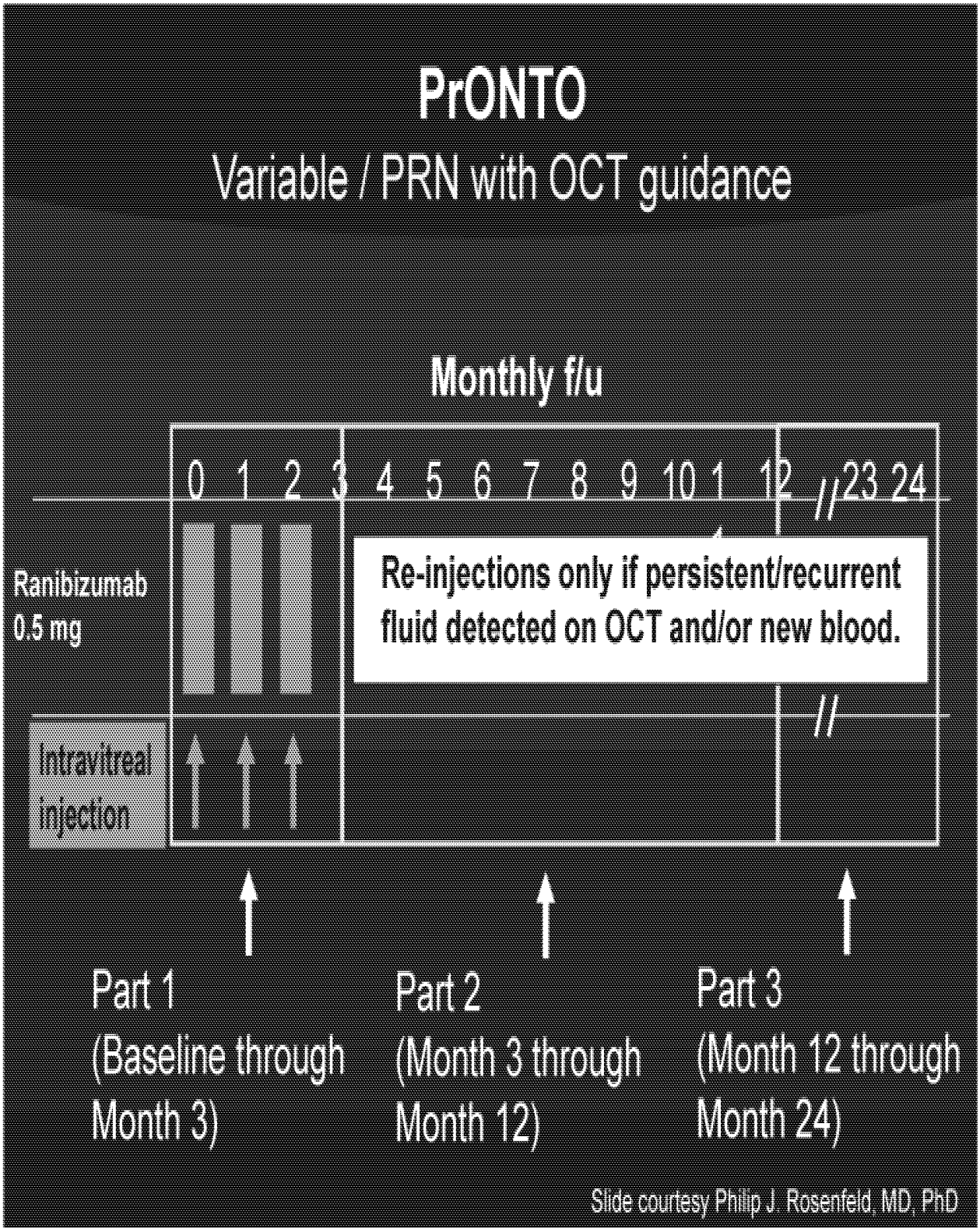
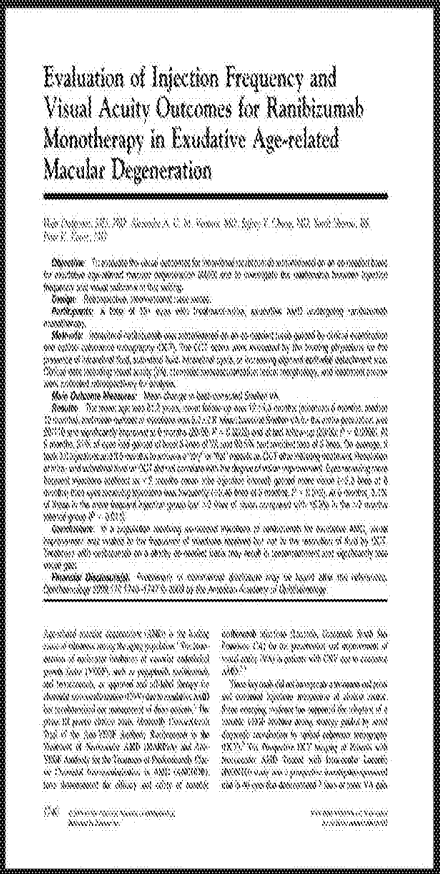

PrONTO
Variable / PRN with OCT guidance
Monthly f/u
0 1 2 3 4 5 6 7 8 9 10 11 12 // 23 24
Ranibizumab 0.5 mg
Re-injections only if persistent/recurrent fluid detected on OCT and/or new blood.
Intravitreal injection
Part 1 (Baseline through Month 3)
Part 2 (Month 3 through Month 12)
Part 3 (Month 12 through Month 24)
Slide courtesy Philip J. Rosenfeld, MD, PhD

Real World Review

Retrospective review



Evaluation of Injection Frequency and Visual Acuity Outcomes for Ranibizumab Monotherapy in Exudative Age-related Macular Degeneration

Retrospective review

Results of One-Year's Treatment with Ranibizumab for Exudative Age-related Macular Degeneration in a Clinical Setting

- •Prevention of moderate vision loss obtained
- •"Far less" robust visual acuity gains

12

Bad Things Can Come to Those Who Wait

MACULAR HEMORRHAGE IN NEOVASCULAR AGE-RELATED MACULAR DEGENERATION AFTER STABILIZATION WITH ANTIANGIOGENIC THERAPY

JONATHAN P. LEVINE, MD,* INNA MARCUS, MD,†
JOHN A. ROBINSON, MD,‡ RICHARD F. SPAIDE, MD,§
MICHAEL J. COUNEY, MD, MBA,‡‡ R. BAILEY FREUND, MD,§§

Purpose: To study patients with neovascular age-related macular degeneration (AMD) who experienced a macular hemorrhage after stabilization with intravitreal anti-vascular endothelial growth factor (anti-VEGF) agents to improve current treatment regimens and prevent disease progression.

Methods: Retrospective chart review of six patients. The main outcome measures included time between last intravitreal anti-VEGF treatment and date of hemorrhage, time between last office visit and date of hemorrhage, and visual acuity before and after hemorrhage.

Results: Three of 6 eyes had a macular hemorrhage within 4 weeks of a stable examination. One eye had optical coherence tomography (OCT) that demonstrated no fluid 1 day before the macular hemorrhage. The average time between the time of the last injection and macular hemorrhage was 16.8 weeks (range, 7.3–29.8 weeks). The average time between the last stable examination and an event was 4.2 weeks (range, 1 day to 7.3 weeks). Three of six patients had a persistent decline in vision after the hemorrhage. Among the 4 patients who had better than 20/200 vision before the macular hemorrhage, 2 dropped to 20/200 or worse.

Conclusion: Eight-threatening macular hemorrhages from AMD can occur within days to weeks after a stable examination and absence of fluid on OCT. Regimens that treat "as needed" based on clinical findings and OCT may not be appropriate for certain patients.

RETINA 29:1074–1079, 2009

Bevacizumab and ranibizumab have been welcomed as breakthrough antiangiogenic therapies for the treatment of neovascular AMD.[1–4] The gloves fifth-series of treatments demonstrated the efficacy of monthly intravitreal injections to improving visual outcomes in eyes with neovascular AMD for up to 2 years. More recently, the PRONTO trial, a small non-randomized study, suggested that a variable dosing regimen, using OCT as a guide for retreatment, could also achieve good visual results with the advantage of fewer treatments than a monthly dosing regimen.[5] Despite the efficacy of existing regimens, sight-threatening recurrences of macular exudation remain a concern for the treating physician. Furthermore, although OCT has become the standard of care for monitoring patients receiving anti-VEGF therapy, it remains an imprecise whether OCT will reliably detect evidence of recurrent neovascular activity before a recently significant macular hemorrhage.

We present a case series of six eyes with neovascular AMD stabilized after intravitreal bevacizumab or ranibizumab treatment that subsequently developed a sight-threatening macular hemorrhage.

Methods

We reviewed the records of six patients with a history of neovascular AMD at one clinical center

From the *Albert Einstein College of Medicine, Bronx, New York; †New York Polyclinic School of Medicine, Stevenson-Rosenthal Consultants of New York, and ‡The Lebanon T. Marie Bernard Bowman Center, Manhattan Eye, Ear, and Throat Hospital, New York, New York.

Supported in part by The Lebanon T. Marie Bernard Bowman Center of the Manhattan Eye, Ear, & Throat Hospital and The Morrill Foundation, Inc.

Reprint requests: R. Bailey Freund, MD, Vitreoretinal Macular Consultants of New York, 460 Park Avenue, 5th Floor, New York, NY 10022; e-mail: rbaileyf@aol.com

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Submacular Hemorrhages during PRN Treatment

- 6 eyes stabilized with anti-VEGF therapy
- No sign of neovascular activity on exam or OCT
- Average time between hemorrhage and last injection: 16 weeks (range 7-29)
- Average time between hemorrhage and last examination: 4 weeks (range 1 day-7 weeks)
  - 3/6 had a hemorrhage within 4 weeks
  - 1 patient had a fluid-free OCT 1 day earlier

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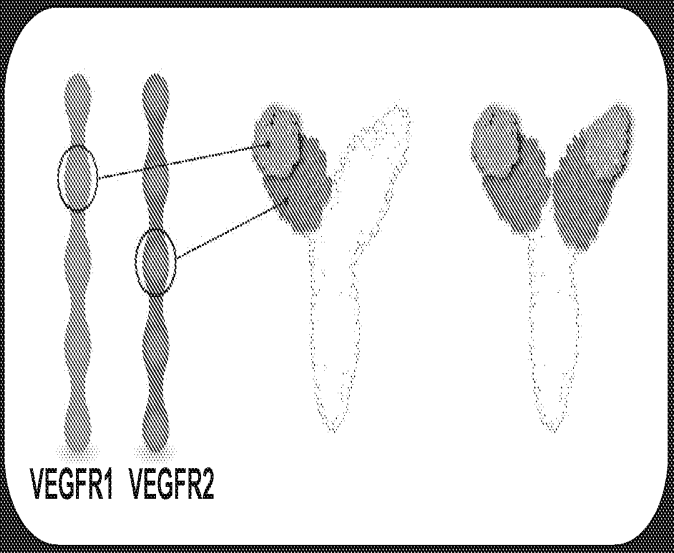
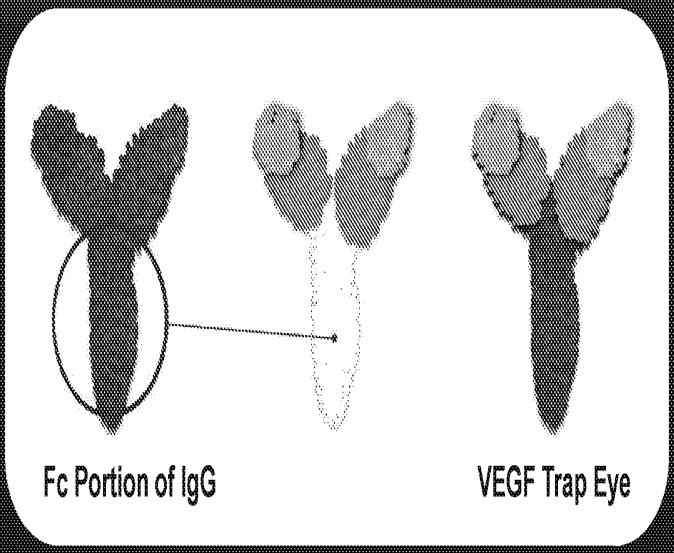
VEGF Trap-Eye:

Specifically Designed to Block Members of the VEGF Family





- **Fusion protein** of key domains from human VEGF receptors 1 and 2 with human IgGFc
- **Blocks all VEGF-A** isoforms and placental growth factor (**PlGF**)
- **High affinity** - binds VEGF-A and PlGF more tightly than native receptors
- Contains **all human** amino acid sequences
- VEGF Trap-Eye is **specially purified and formulated** for intravitreal injection

IgG=immunoglobulin G

VEGF Trap-Eye Binding

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VEGF Trap-Eye Potently Blocks VEGF-A and Uniquely Binds PlGF

	VEGFR1 cell line			VEGFR2 cell line	
	IC_{50} at 20pM VEGF-A_{121}	IC_{50} at 20pM VEGF-A_{165}	IC_{50} at 40pM hPlGF2	IC_{50} at 20pM VEGF-A_{121}	IC_{50} at 20pM VEGF-A_{165}
VEGF Trap	15 pM	16 pM	2890 pM	15 pM	26 pM
bevacizumab	854pM	1476 pM	NB	706 pM	1323 pM
ranibizumab	675 pM	1140 pM	NB	686 pM	845 pM

NB: no detectable blocking under the assay conditions used

Data on file, Regeneron Pharmaceuticals, Inc.

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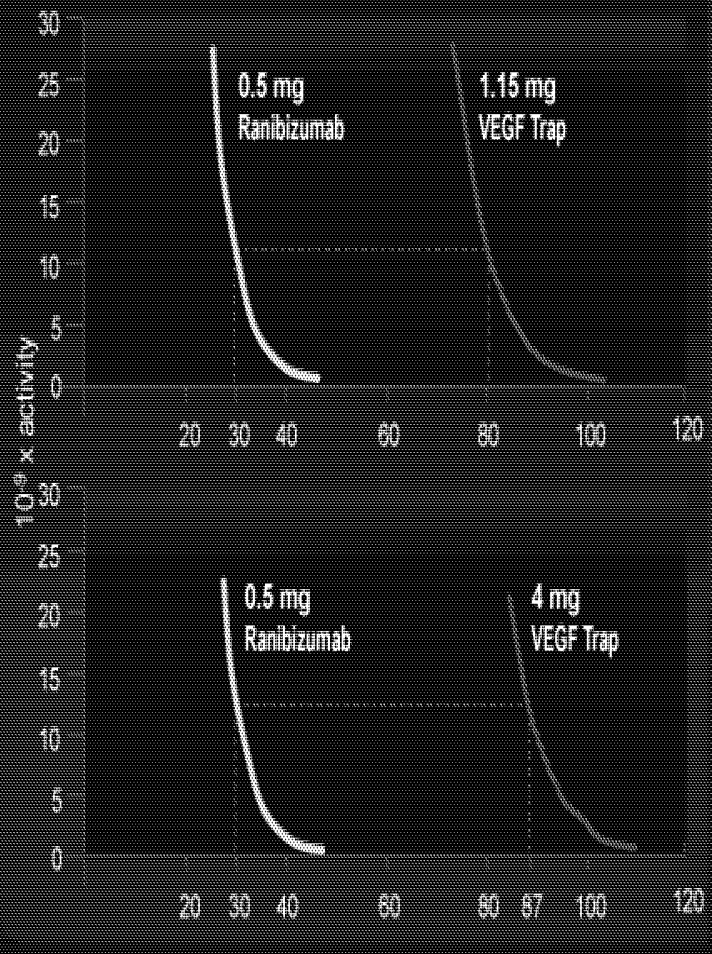
Modeling of Prolonged Biological Activity of Intravitreal VEGF Trap-Eye



VEGF Trap 1.15mg at 79 days ≅ ranibizumab 0.5mg at 30 days*

VEGF Trap 4mg at 87 days ≅ ranibizumab 0.5mg at 30 days*

*By extrapolation, VEGF Trap-Eye 2 mg at 83 days ≅ ranibizumab 0.5mg at 30 days**

MW Stewart, PJ Rosenfeld. Br J *Ophthalmol* 2008;92:667–668.

*Est. biologic activity

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Potential Role of PlGF in Angiogenesis

Placental Growth Factor (PlGF)-Deficient Mice Show Delays in Normal Retinal Vascular Development and Reduced Vascular Abnormalities in Oxygen-Induced Retinal Ischemia

E. Cheung, K. Myers, G.D. Yancopoulos, I.B. Lobov, S.J. Wiegand.
Ophthalmology, Regeneron Pharmaceuticals, Tarrytown, NY

ARVO, 2009 Poster # A462

Conclusion:

This study establishes a role for PlGF in normal retinal vascular development, as well as in the response to retinal ischemia. ***These results are consistent with observations in other disease models, which suggest that PlGF inhibition may ameliorate pathological angiogenesis.***

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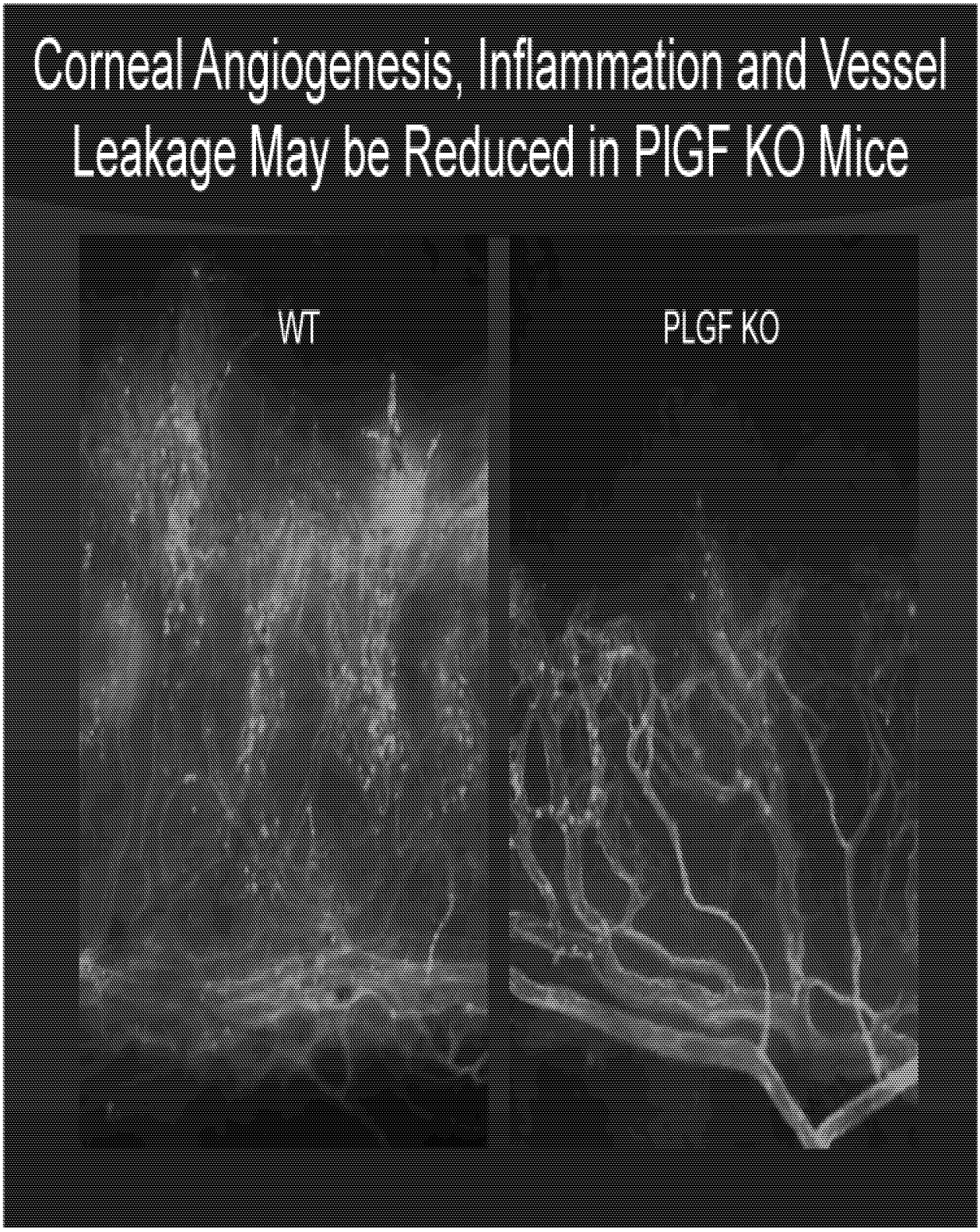
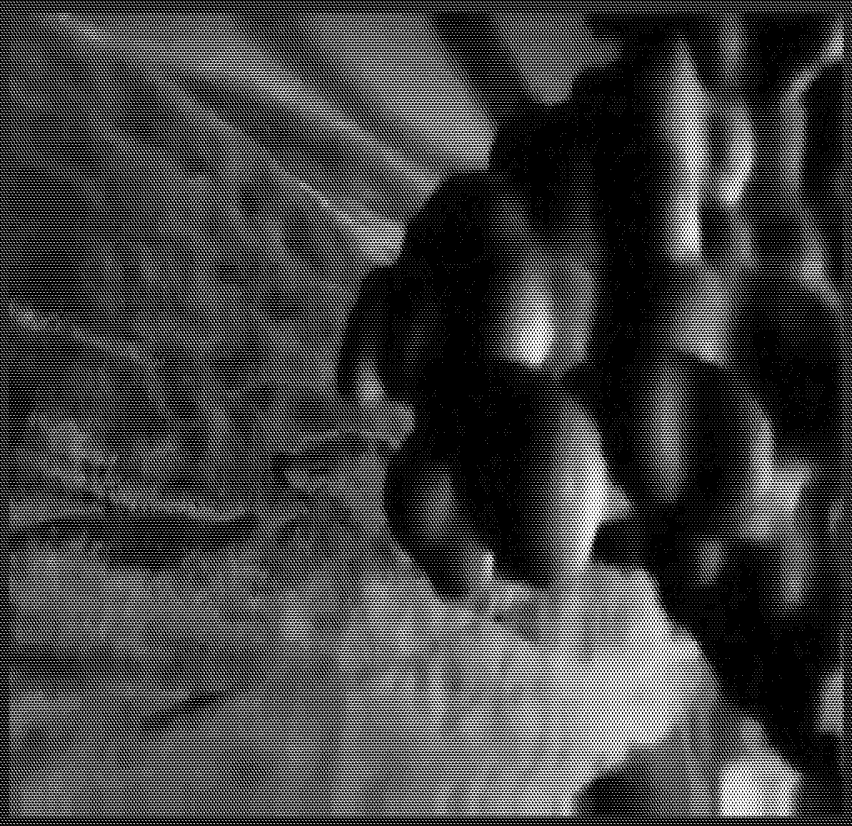
Corneal Angiogenesis, Inflammation and Vessel Leakage May be Reduced in PlGF KO Mice



Role of PlGF in Angiogenesis



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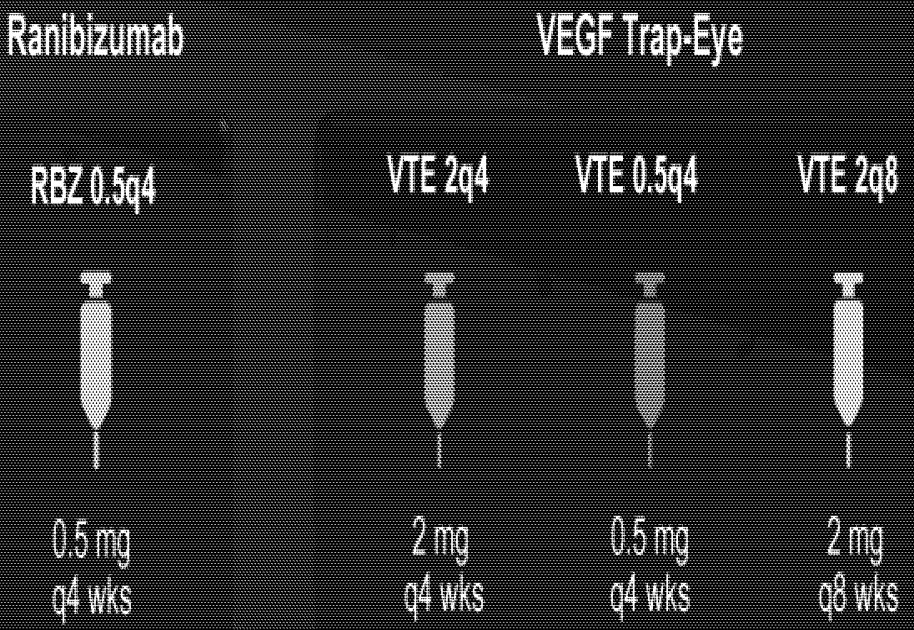
VIEW 1 & 2

Study Design

Multi-center, active controlled, double masked trial

Patients randomized 1:1:1:1

VIEW 1: N=1217



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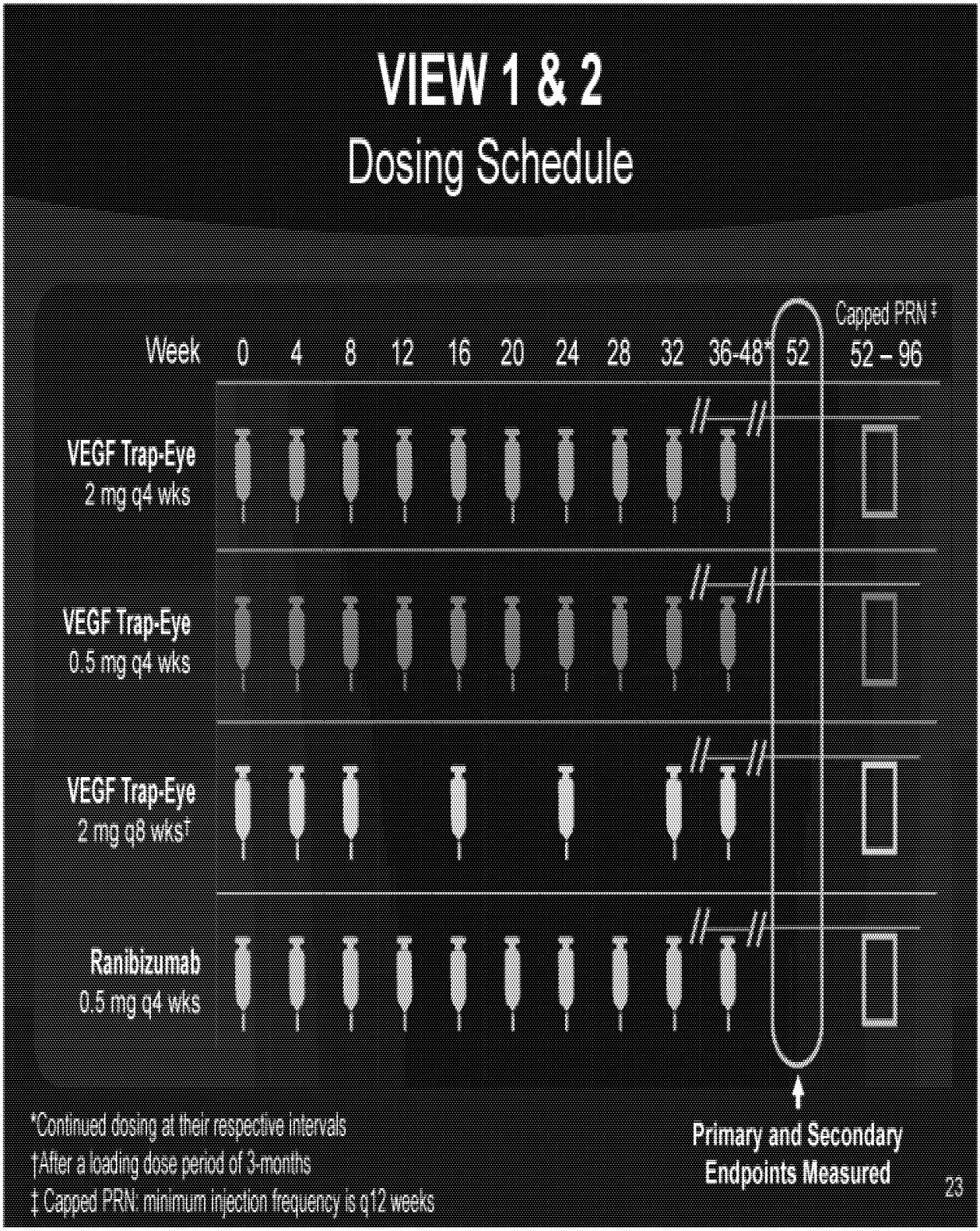
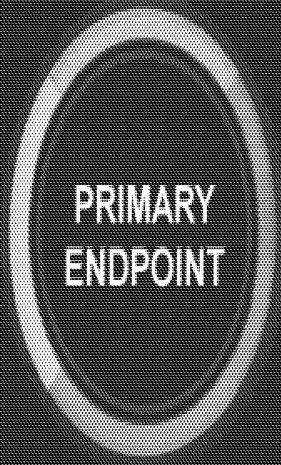
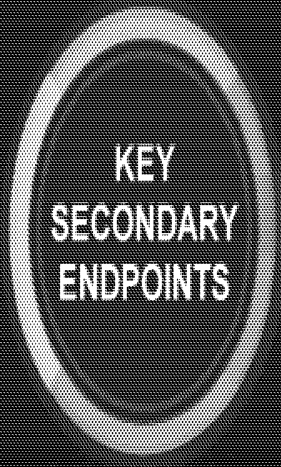

VIEW 1 & 2
Dosing Schedule
Week
0
4
8
12
16
20
24
28
32
36–48*
52
Capped PRN ‡
52 – 96
VEGF Trap-Eye
2 mg q4 wks
VEGF Trap-Eye
0.5 mg q4 wks
VEGF Trap-Eye
2 mg q8 wks†
Ranibizumab
0.5 mg q4 wks
*Continued dosing at their respective intervals
†After a loading dose period of 3-months
‡ Capped PRN: minimum injection frequency is q12 weeks
Primary and Secondary
Endpoints Measured
23

VIEW 1 & 2

Study Endpoints



- Proportion of patients with prevention of moderate vision loss (< 15 letters lost on EDTRS eye chart)



- Mean change in visual acuity
- Proportion of patients who gain at least 15 letters of vision

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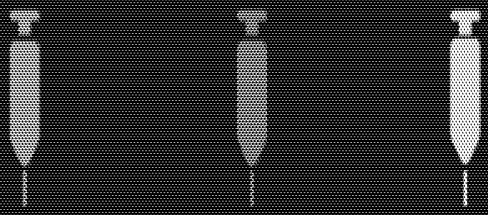
VIEW 1 & 2
Statistical Testing

PRIMARY ENDPOINT

Primary Endpoint tested using a non-inferiority paradigm with the non-inferiority margin set at 10%

Multiplicity controlled using a conditional sequence of confidence intervals as follows:



VTE 2q4
2 mg q4 wks

VTE 0.5q4
0.5 mg q4 wks

VTE 2q8
2 mg q8 wks

VTE considered non-inferior to RBZ if the confidence interval of the difference between RBZ and VTE lies entirely below 10%

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Statistical Rationale Behind the VIEW Program

- Objective: prove that VTE was non-inferior to RBZ
- Primary endpoint: the prevention of vision loss of greater than or equal to 15 letters on the ETDRS chart
- Non-inferiority was chosen for the following reasons:
  - Highly effective treatment available
- Data from previous Phase 3 Ranibizumab studies in AMD used to establish margin
- The non-inferiority margin was set at -10% from the "no difference line"

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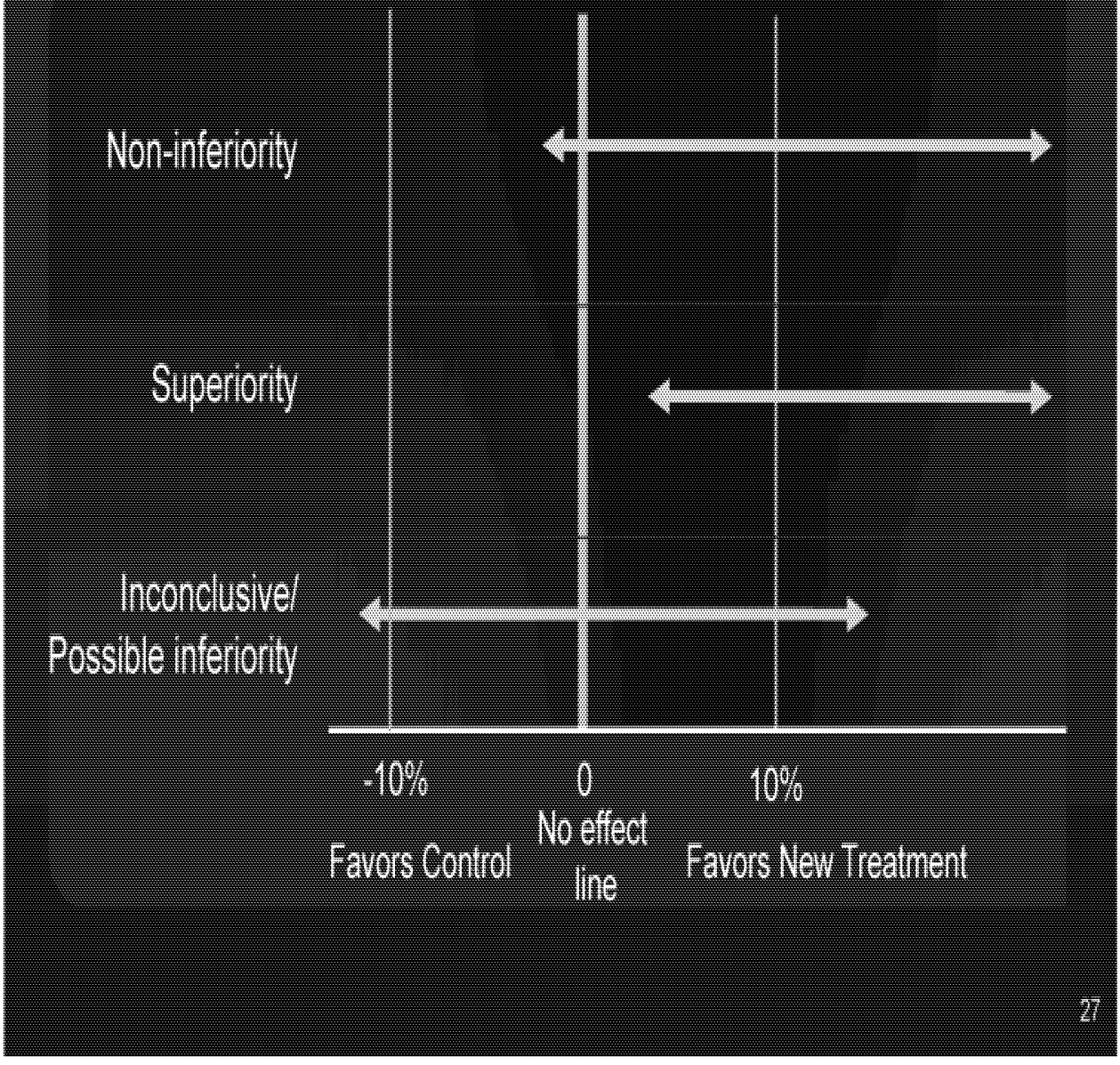
Illustrations of Superiority and Non-Inferiority



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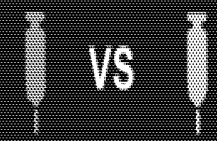
VIEW 1 & 2

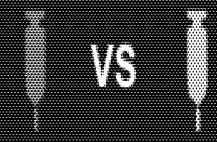
Statistical Testing

KEY SECONDARY ENDPOINTS

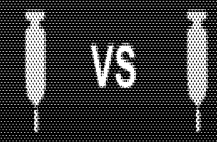
Key secondary endpoints tested for superiority using a conditional sequence of statistical hypothesis tests to control for multiplicity



VTE 2q4 RBZ 0.5q4



VTE 0.5q4 RBZ 0.5q4



VTE 2q8 RBZ 0.5q4

Mean change in visual acuity

Proportion of patients who gain at least 15 letters of vision

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VIEW 1
Patient Disposition

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
Randomized	306 (100%)	304 (100%)	304 (100%)	303 (100%)
Completed Week 52	284 (92.8%)	293 (96.4%)	277 (91.1%)	276 (91.1%)
Discontinuation Before Wk 52	22 (7.2%)	11 (3.6%)	27 (8.9%)	27 (8.9%)
Withdrawal Of Consent	10 (3.3%)	5 (1.6%)	7 (2.3%)	8 (2.6%)
Protocol Deviation	3 (1.0%)	0	3 (1.0%)	1 (0.3%)
Adverse Event	4 (1.3%)	3 (1.0%)	5 (1.6%)	4 (1.3%)
Discontinuation due to Death*	3 (1.0%)	1 (0.3%)	2 (0.7%)	7 (2.3%)
Lost To Follow-Up	1 (0.3%)	2 (0.7%)	4 (1.3%)	4 (1.3%)
Lack of efficacy	0	0	2 (0.7%)	2 (0.7%)
Other†	1 (0.3%)	0	4 (1.3%)	1 (0.3%)

*Total number of deaths: Rq4: 5 (1.6%), 2q4: 2 (0.7%), 0.5q4: 2 (0.7%), 2q8: 8 (2.6%)
†Investigator decision, no leakage, non compliance, health issues, patient decision

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VIEW 1

Baseline Demographics

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
n (full analysis set)	304	304	301	301
Mean Age (years)	78.2 ± 7.6	77.7 ± 7.9	78.4 ± 8.0	77.9 ± 8.4
Gender				
Women (%)	56.6%	63.8%	55.5%	59.1%
Men (%)	43.4%	36.2%	44.5%	40.9%
Race (%)				
White	97.4%	97.0%	96.7%	95.3%
Other	1.3%	1.3%	2.4%	2.2%
Not Reported/Multi Racial	1.3%	1.6%	1%	2.3%

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VIEW 1

Baseline Disease Characteristics

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
n (full analysis set)	304	304	301	301
ETDRS BCVA (letter score±SD)	54 ± 13	55 ± 13	56 ± 13	56 ± 13
Snellen Equivalent	20/80	20/80	20/80	20/80
Lesion Type: (%)				
Predominantly Classic	27.0%	28.6%	26.9%	23.6%
Minimally Classic	33.2%	34.5%	32.2%	36.5%
Occult no classic	37.8%	36.2%	40.2%	39.2%
Lesion Size (mm^2, mean ± SD)	7.0 ± 5.5	7.0 ± 5.4	7.0 ± 4.7	7.0 ± 5.2
Total Retina/LesionThickness (µm ± SD)	493 ± 183	476 ± 163	482 ± 182	496 ± 181

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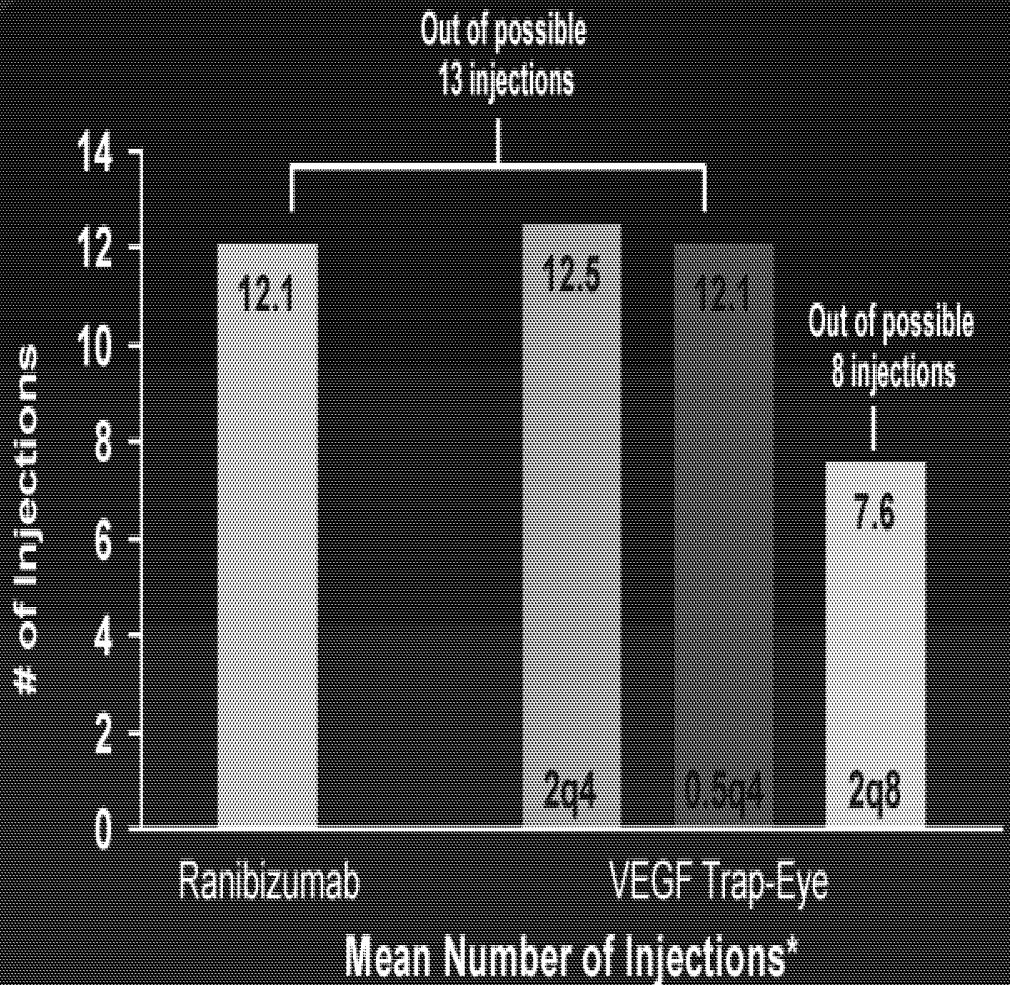
VIEW 1

Number of Active Injections Through 1 Year



*Out of possible 13 for Q4 groups and 8 for Q8 group

Full analysis set; Rq4 n=304; 2q4 n=304; 0.5q4 n=301; 2q8 n=301;

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Visual Acuity

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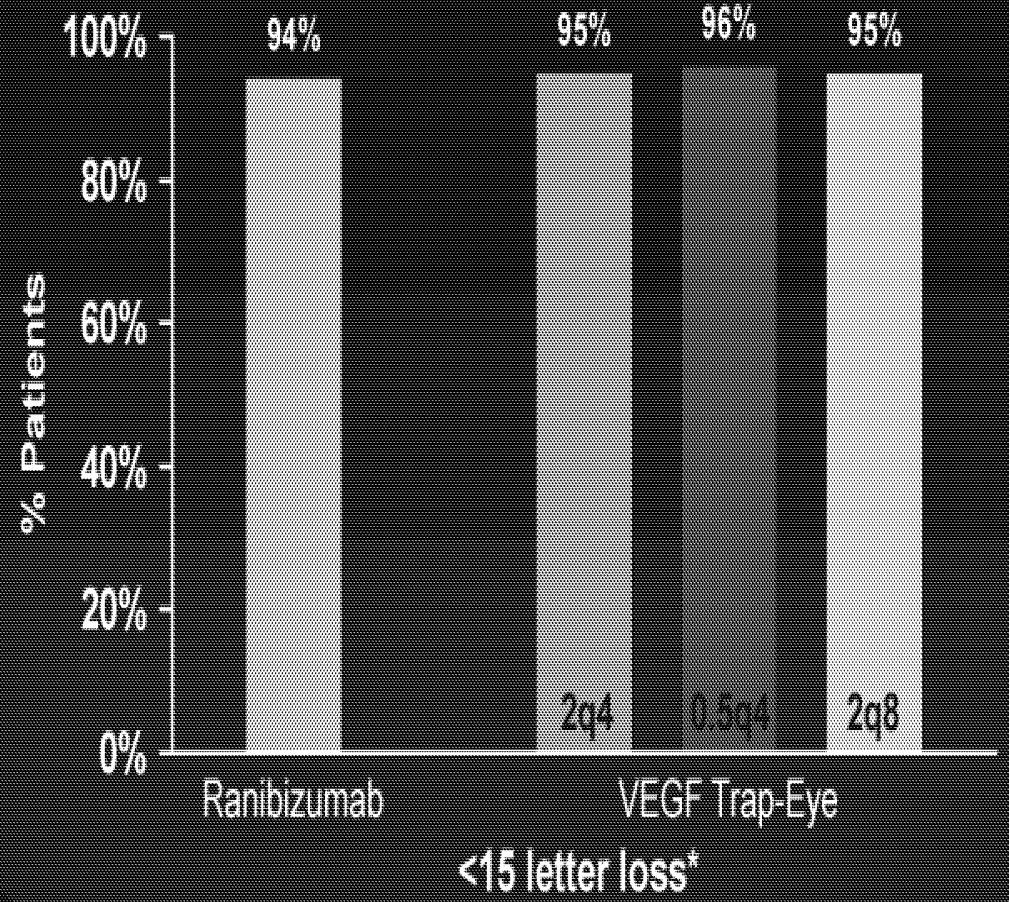
VIEW 1 Study

Primary Endpoint: Maintenance of Vision at 1 Year

All doses of VEGF Trap-Eye were non-inferior to ranibizumab



*Compared to baseline; LOCF; per protocol set: Rq4 n=269; 2q4 n=285; 0.5q4 n=270; 2q8 n=265

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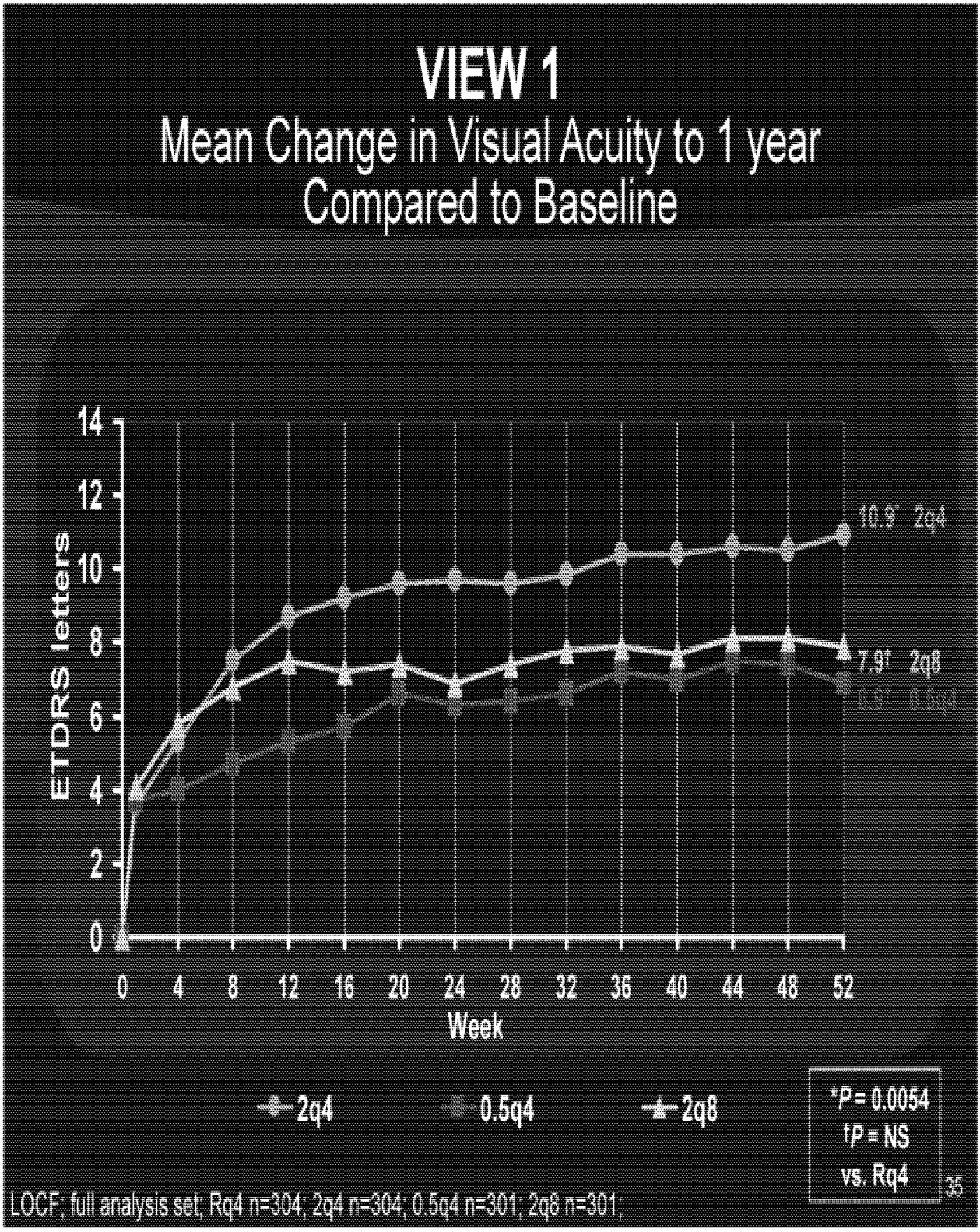
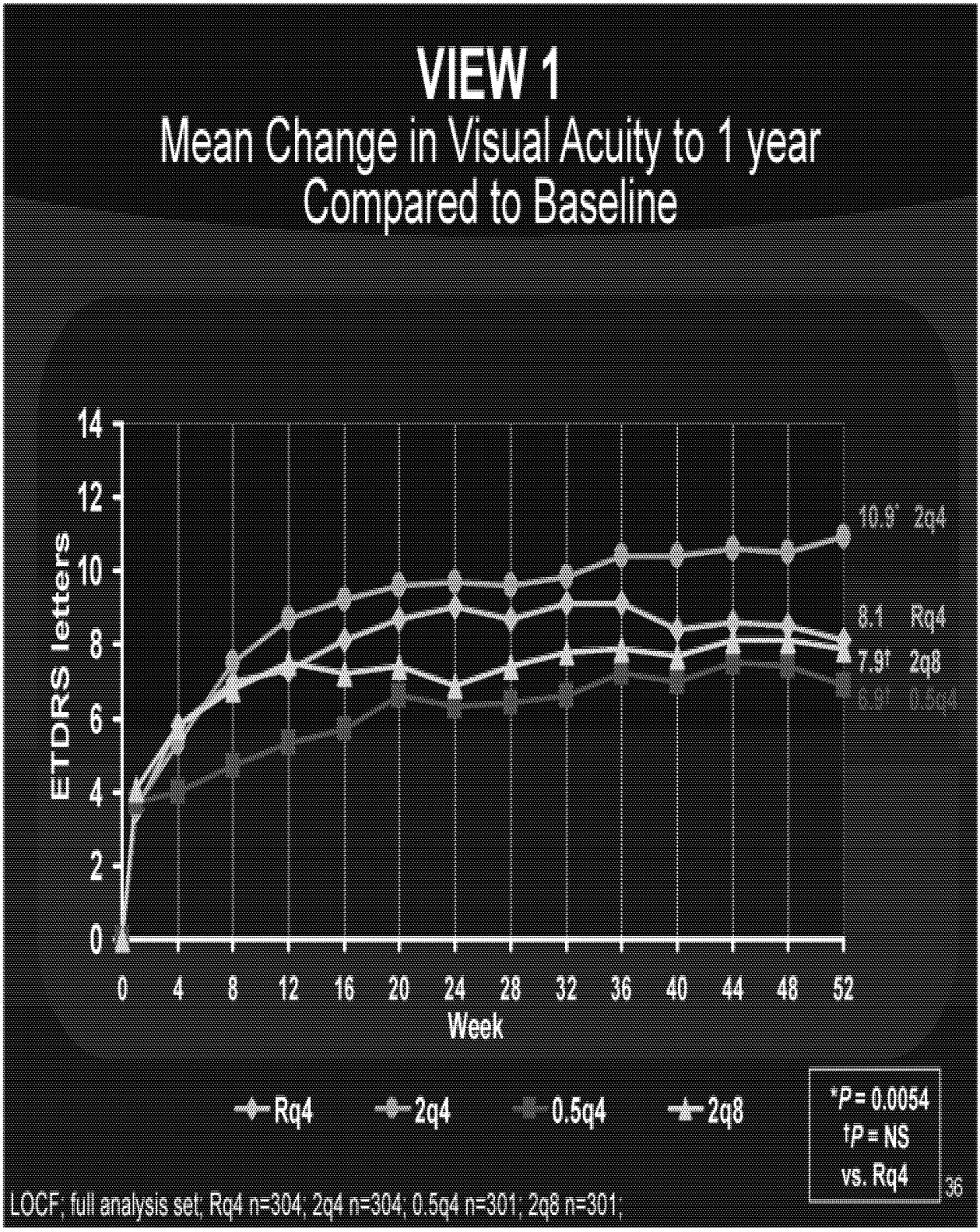
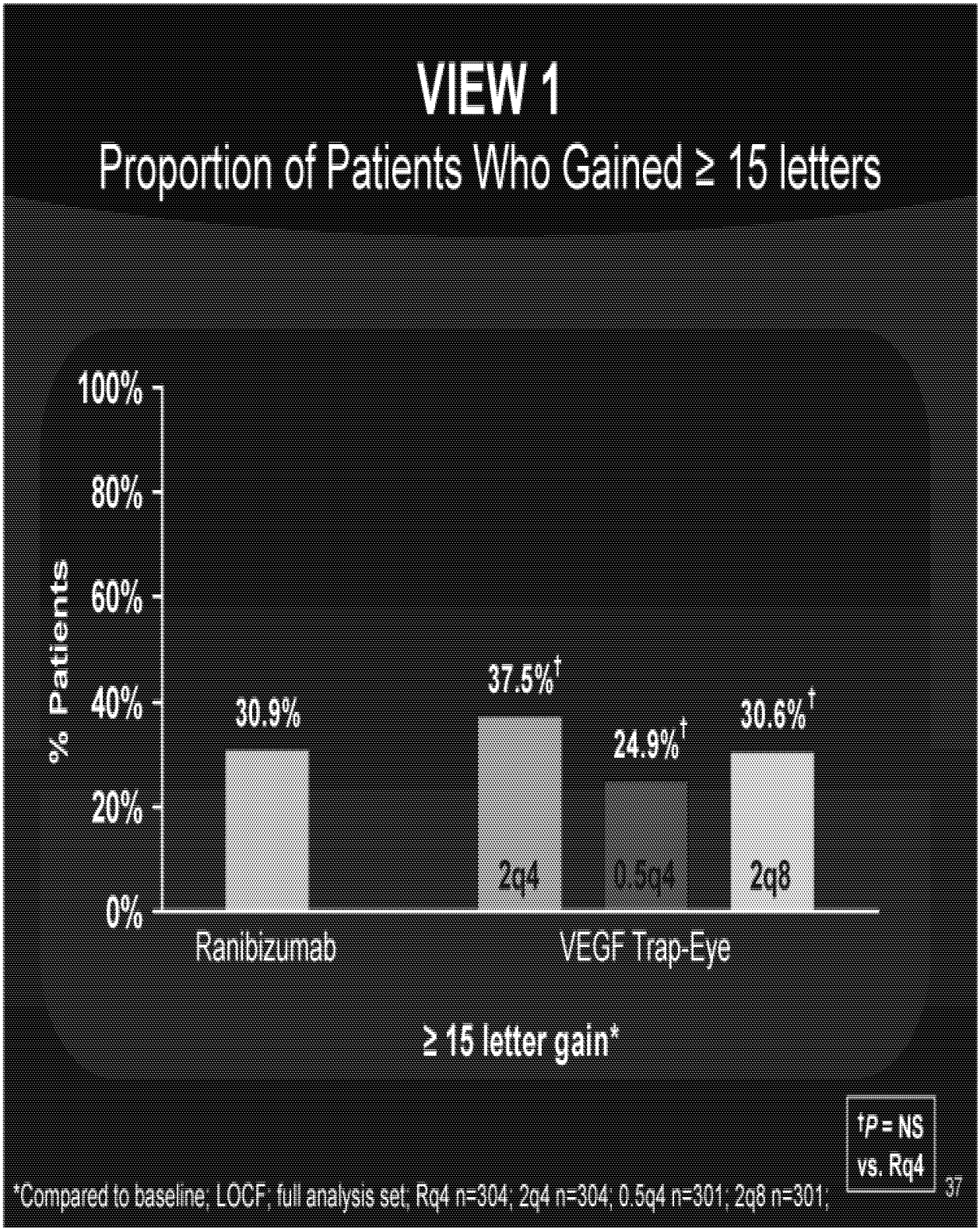

VIEW 1
Mean Change in Visual Acuity to 1 year
Compared to Baseline
ETDRS letters
14
12
10
8
6
4
2
0
0
4
8
12
16
20
24
28
32
36
40
44
48
52
Week
10.9* 2q4
7.9† 2q8
2q4
0.5q4
2q8
*P = 0.0054
†P = NS
vs. Rq4
LOCF; full analysis set; Rq4 n=304; 2q4 n=304; 0.5q4 n=301; 2q8 n=301;
35


VIEW 1
Mean Change in Visual Acuity to 1 year
Compared to Baseline
ETDRS letters
14
12
10
8
6
4
2
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Week
10.9* 2q4
8.1 Rq4
7.9† 2q8
Rq4
2q4
0.5q4
2q8
*P = 0.0054
†P = NS
vs. Rq4
LOCF; full analysis set; Rq4 n=304; 2q4 n=304; 0.5q4 n=301; 2q8 n=301;
36



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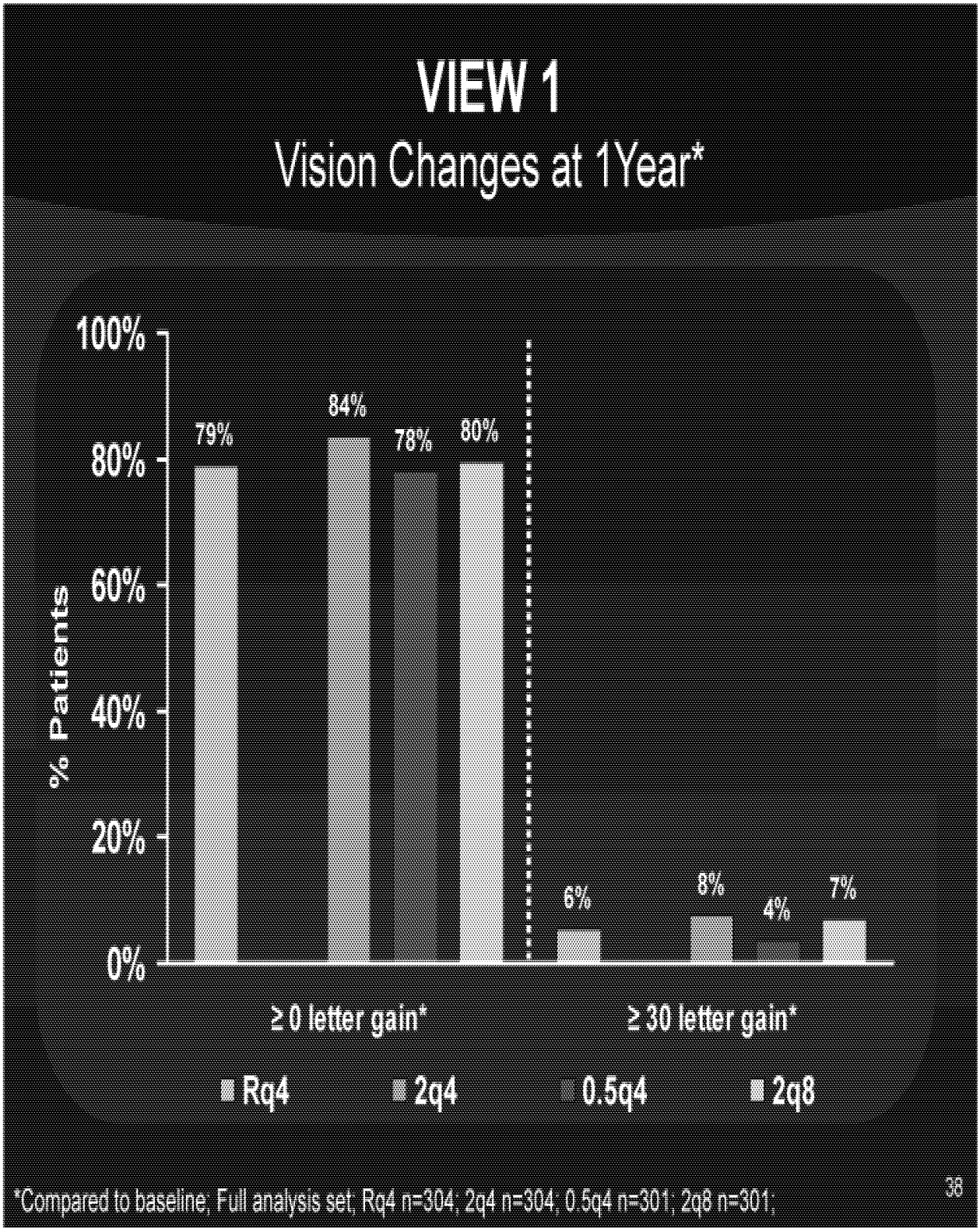

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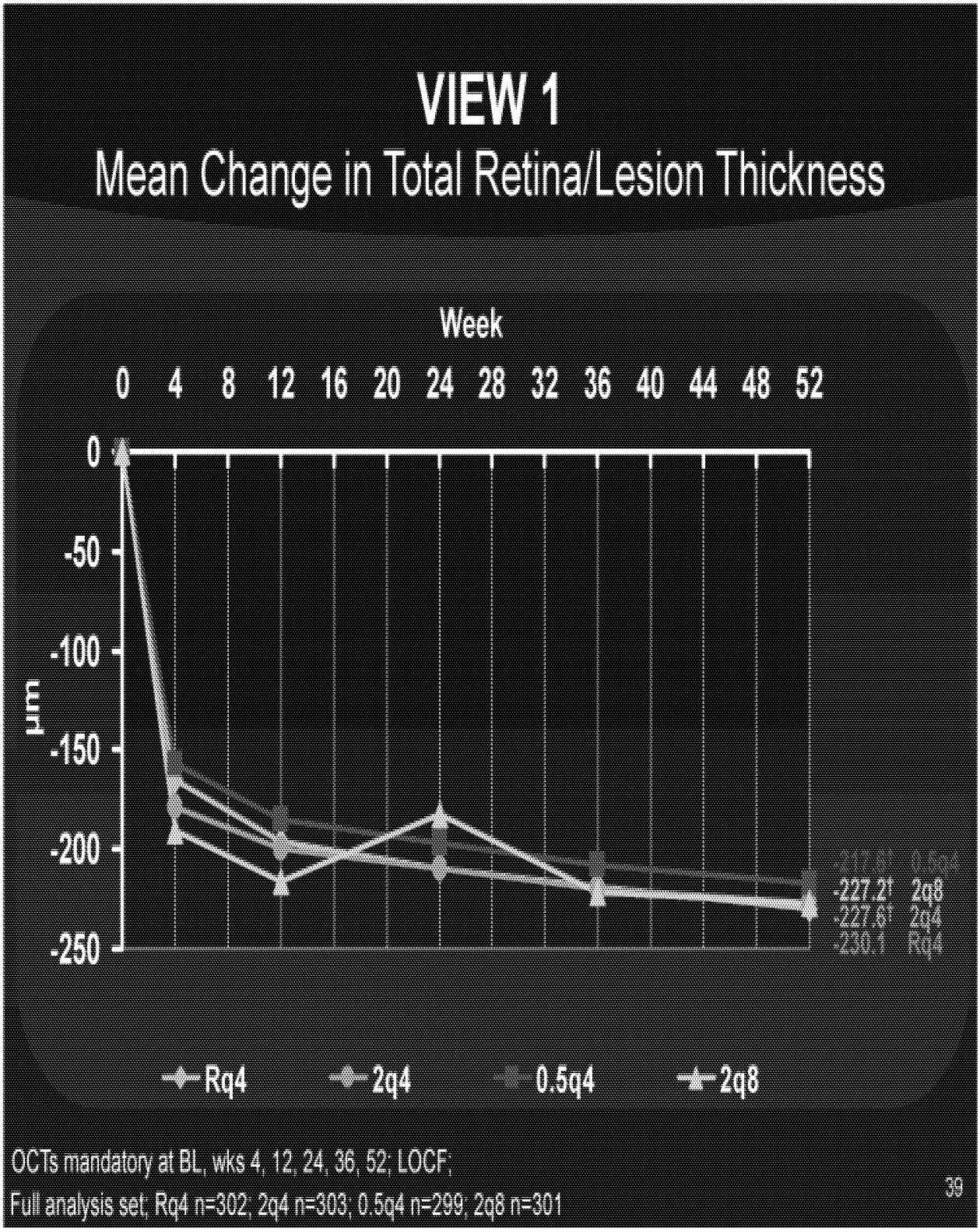
VIEW 1
Mean Change in Total Retina/Lesion Thickness
Week
0 4 8 12 16 20 24 28 32 36 40 44 48 52
0
-50
-100
-150
-200
-250
µm
-227.2† 2q8
-227.6† 2q4
-230.1 Rq4
Rq4
2q4
0.5q4
2q8
OCTs mandatory at BL, wks 4, 12, 24, 36, 52; LOCF;
Full analysis set; Rq4 n=302; 2q4 n=303; 0.5q4 n=299; 2q8 n=301
39

Safety

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VIEW 1

% Patients with Study Eye Ocular Serious Adverse Events

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
n (safety analysis set)	304	304	304	303	911
# subjects with at least 1 SAE	9 (3.0%)	7 (2.3%)	5 (1.7%)	3 (1.0%)	15 (1.6%)
Endophthalmitis	3 (1.0%)	3 (1.0%)	0	0	3 (0.3%)
Culture positive	1	2			
Culture negative	1	1			
Unknown	1				
Visual acuity reduced	2 (0.7%)	1 (0.3%)	2 (0.7%)	0	3 (0.3%)
Retinal hemorrhage	2 (0.7%)	0	0	2 (0.7%)	2 (0.2%)
Angle closure glaucoma	0	1 (0.3%)	0	0	1 (0.1%)
Cataract	0	0	1 (0.3%)	0	1 (0.1%)
Keratitis	0	1 (0.3%)	0	0	1 (0.1%)
Macular hole	0	0	1 (0.3%)	0	1 (0.1%)
Retinal degeneration	0	1 (0.3%)	0	0	1 (0.1%)
Retinal detachment	0	0	1 (0.3%)	0	1 (0.1%)
Retinal edema	0	0	1 (0.3%)	0	1 (0.1%)
RPE tear	0	0	0	1 (0.3%)	1 (0.1%)
Retinal tear	1 (0.3%)	0	0	0	0
Incorrect dose administered	1 (0.3%)	0	0	0	0
IOP increased	1 (0.3%)	0	0	0	0

41

VIEW 1

Deaths

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
N (safety analysis set)	304	304	304	303	911
All Deaths*	5 (1.6%)	2 (0.7%)	2 (0.7%)	8 (2.6%)	12 (1.3%)
Myocardial Infarction	1	0	1	2	3
Stroke	0	0	0	1	1
Cerebral Hemorrhage	0	0	1	0	1
Ruptured AAA	0	0	0	1	1
Congestive Heart Failure	1	0	0	2	2
Respiratory (Pneumonia and COPD)	1	1	0	1	2
Cancer Related	2	1	0	1	2

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VIEW 1

% Patients with APTC Events through 1 Year

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
N (safety analysis set)	304	304	304	303	911
Any APTC event	5 (1.6%)	2 (0.7%)	7 (2.3%)	6 (2.0%)	15 (1.6%)
Vascular Deaths	1 (0.3%)	0	1 (0.3%)	4 (1.3%)	5 (0.5%)
Non Fatal MI	4 (1.3%)	1 (0.3%)	4 (1.3%)	1 (0.3%)	6 (0.7%)
Non Fatal Stroke[a]	0	1 (0.3%)	2 (0.7%)	1 (0.3%)	4 (0.4%)

[a]All non fatal strokes were ischemic in nature

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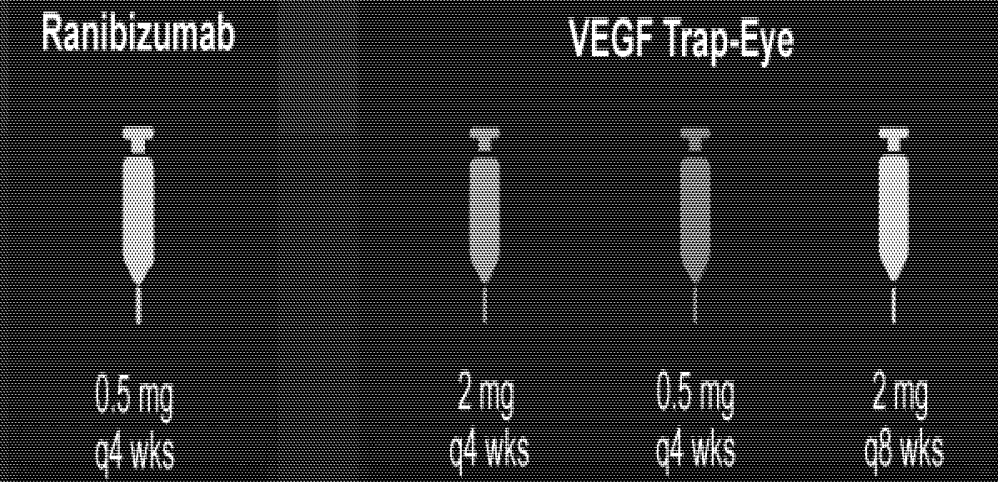
VIEW 1
Conclusions

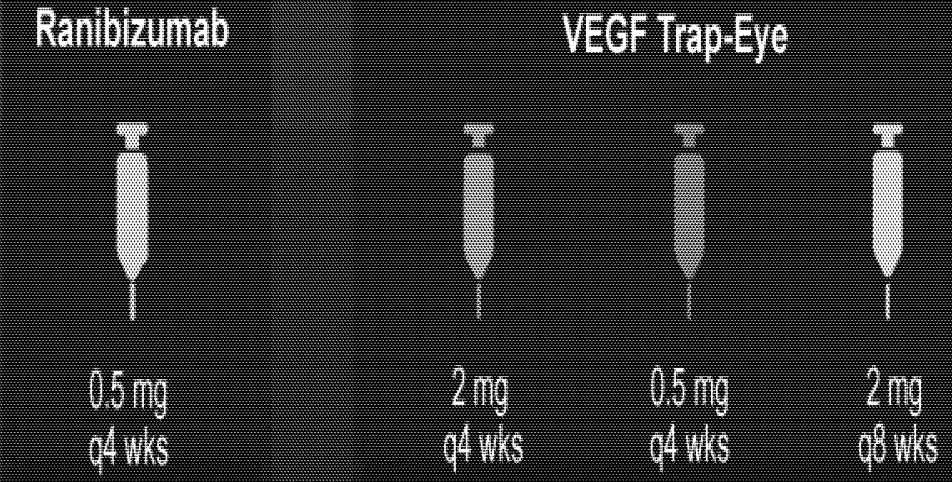
- VEGF Trap-Eye (0.5 mg or 2 mg monthly, and 2 mg every other month) was comparable to 0.5 mg monthly Ranibizumab



44

VIEW 1
Conclusions

- VEGF Trap-Eye was well-tolerated across all doses and dose regimens
  - Similar ocular and systemic safety profile as ranibizumab



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Conclusions

VEGF Trap-Eye offers the potential of outstanding visual and anatomic outcomes of anti-VEGF therapy that we have come to expect, with a significant decrease in the treatment burden that patients, their families, and clinicians have come to endure.

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Vascular Endothelial Growth Factor (VEGF) Trap-Eye 1-Year Results:

Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD)

VIEW 2

Ursula Schmidt-Erfurth
Department of Ophthalmology
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Financial Disclosures

- Consultant for Alcon, Allergan, Bayer, Carl Zeiss Meditec, Genentech, Novartis, Pfizer
- Performing contract research for Alcon, Bayer and Novartis
- Under the guidelines of the Medical University of Vienna

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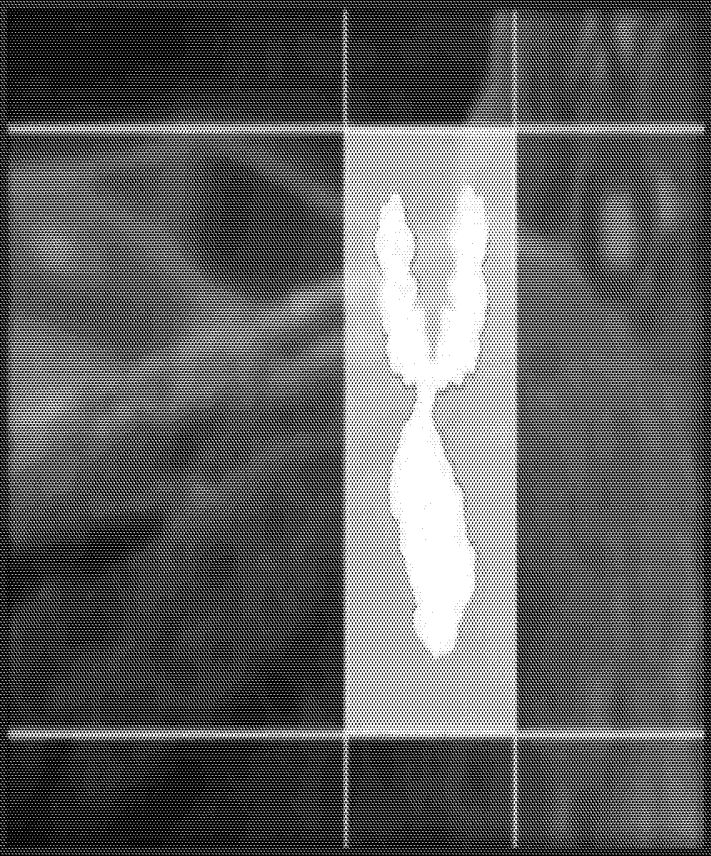
VEGF Trap Concept

- VEGF trap (aflibercept) is a designed fusion protein:

  A chimeric soluble decoy receptor moiety composed of the extracellular domains of VEGF receptor 1 and 2 fused to the Fc part of human IgG1

VEGF Trap Concept



VEGF Trap Concept

- Role of the Fc portion is to prolong the half-life due to the interaction of Fc with the neonatal FcRn receptor

- The characteristics of the fusion protein are:
  - binding to all VEGF isoforms: VEGF A, B, C
  - binding of placental growth factor (PlGF)
  - 10 fold higher affinity than bevacizumab
  - no cross-reaction with any tyrosine kinase receptor
  - induction of rapid endothelial cell death

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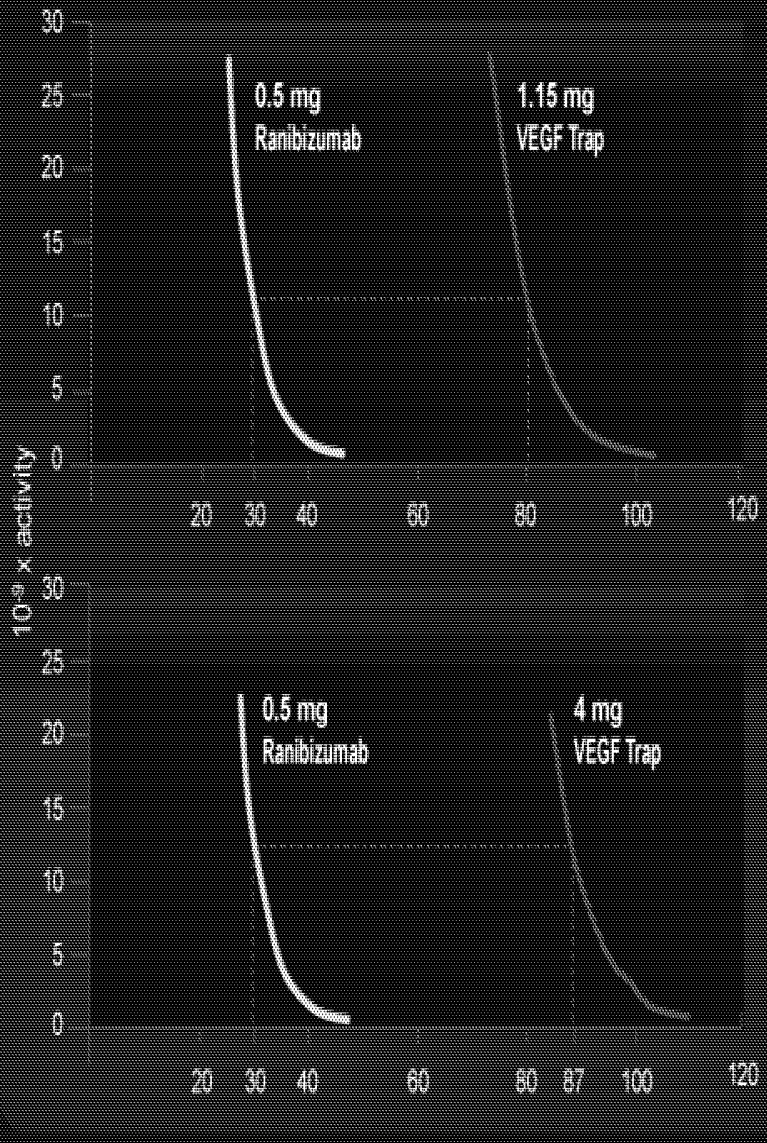
Modeling of Prolonged Biological Activity of Intravitreal VEGF Trap-Eye



- Biological activity of equimolar VEGF Trap 1.15mg at 79 days comparable to ranibizumab 0.5mg at 30 days
- Biological activity of VEGF Trap 4mg at 87 days is comparable to that of ranibizumab 0.5mg at 30 days

Based on this model, 2 mg VEGF Trap-Eye at 83 days would provide similar biological activity to ranibizumab 0.5 mg at 30 days

MW Stewart, PJ Rosenfeld. Br J *Ophthalmol* 2008;92:667–668.

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Therapeutic fusion proteins on the market

Chemical /Common Name	Brand Name	Target	Structure	Licensed Indication, Target Diseases	Mode of action	Manufacturer and/or Distributor
Abatacept	Orencia	B7-1 (CD80), B7-2 (CD86) costimulatory molecules on APC	CTLA4 (cytotoxic T-lymphocyte antigen-4)-Human IgG1 Fusion protein	Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis	binding to the B7 protein on APCs and preventing them from delivering the costimulatory signal to T cells (CD28), thus preventing the full activation of T cells	Bristol Myers Squibb
Alefacept	Amvive (not EMEA approved)	CD2	LFA-3-IgG1 Fc fusion protein	moderate to severe, chronic plaque psoriasis	Inhibits lymphocyte activation by blocking co-stimulatory molecule interaction LFA-3/CD2, and induces apoptosis in memory-effector T cells	Astellas Pharma Biogen IDEC
Denileukin diftitox	ONTAK	IL-2 Receptor	recombinant fusion protein expressing amino acid residues of diphtheria toxin fragment A & B, followed by the sequence for IL-2	recurrent CD25 positive, cutaneous T-cell lymphoma	The protein binds to IL-2 receptors on T-cells. The diphtheria toxin is then internalized, killing the T-cell.	Eisai
Etanercept	Enbrel	TNFα and TNFβ	TNFR2-IgG1 Fc fusion protein	RA, Juvenile Idiopathic Arthritis psoriatic arthritis, ankylosing spondylitis, plaque psoriasis	TNF inhibitor	Amgen Wyeth
Rilonacept	Arcalyst (Orphan Drug)	IL-1	Extracellular domain of IL1-R and IgG1 Fc	Cryopirin-associated periodic syndromes (CAPS)	Binds and neutralize IL-1	Regeneron

Introduction

- Two identical trials including a total number of 2457 patients with active, treatment-naïve neovascular AMD were performed
- Primary study outcome was defined as non-inferiority between VEGF Trap-Eye (VTE) arms and standard therapy with monthly ranibizumab injections
- Intravitreal VEGF Trap-Eye regimens included 0.5mg and 2mg monthly and 2mg every two months following a loading regimen
- Functional (BCVA) and anatomical (OCT) responses were documented

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VIEW 1 & 2

Study Design

Multi-center, active controlled, double masked trial

Ranibizumab	VEGF Trap-Eye		
RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8
0.5 mg q4 wks	2 mg q4 wks	0.5 mg q4 wks	2 mg q8 wks

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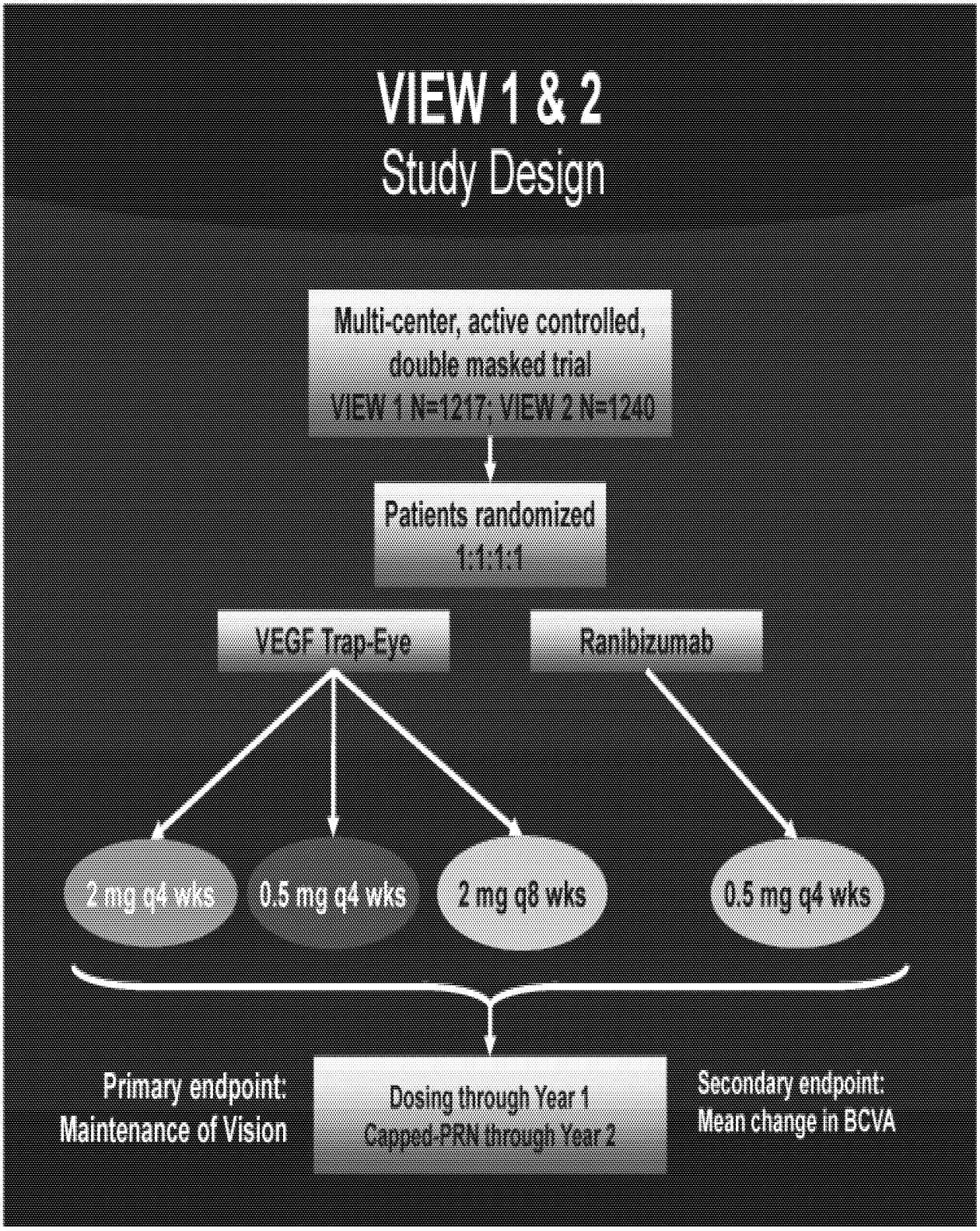
VIEW 1 & 2
Study Design
Multi-center, active controlled, double masked trial
VIEW 1 N=1217; VIEW 2 N=1240
Patients randomized 1:1:1:1
VEGF Trap-Eye
Ranibizumab
2 mg q4 wks
0.5 mg q4 wks
2 mg q8 wks
0.5 mg q4 wks
Primary endpoint: Maintenance of Vision
Dosing through Year 1
Capped PRN through Year 2
Secondary endpoint: Mean change in BCVA

VIEW 2

Patient Disposition

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
Randomized	303 (100%)	313 (100%)	311 (100%)	313 (100%)
Completed Week 52	276 (91.1%)	281 (89.8%)	274 (88.1%)	284 (90.7%)
Discontinuation Before Wk 52	27 (8.9%)	32 (10.2%)	37 (11.9%)	29 (9.3%)
Adverse event	2 (0.7%)	6 (1.9%)	8 (2.6%)	9 (2.9%)
Discontinuation due to Death*	1 (0.3%)	3 (1.0%)	2 (0.6%)	1 (0.3%)
Lost to Follow-up	4 (1.3%)	1 (0.3%)	2 (0.6%)	2 (0.6%)
Other	7 (2.3%)	6 (1.9%)	10 (3.2%)	5 (1.6%)
Protocol Violation	2 (0.7%)	1 (0.3%)	1 (0.3%)	0
Treatment failure	0	0	1 (0.3%)	1 (0.3%)
Withdrawal by subject	11 (3.6%)	15 (4.8%)	13 (4.2%)	11 (3.5%)

*Total number of deaths: Rq4: 2 (0.7%), 2q4: 3 (1.0%), 0.5q4: 2 (0.7%), 2q8: 2 (0.7%)

VIEW 2

Baseline Demographics

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
n (full analysis set)	291	309	296	306
Age (years) ± SD	73.0 ± 9.0	74.1 ± 8.5	74.7 ± 8.6	73.8 ± 8.6
Gender				
Women (%)	58.1%	57.0%	49.7%	57.2%
Men (%)	41.9%	43.0%	50.3%	42.8%
Race (%)				
White	73.2%	73.1%	74.0%	70.9%
Asian	20.6%	21.7%	20.6%	22.5%
Black	0.3%	0	0.3%	0.7%
Not Reported	5.8%	5.2%	5.1%	5.9%

VIEW 1 & 2

Baseline Demographics

	VIEW 1 All Groups	VIEW 2 All Groups
n (full analysis set)	1210	1202
Age (years)	78.1	73.9
Women (%)	58.8%	55.5%
Race (%)		
Caucasian	96.6%	72.8%
Asian	1.0%	21.4%
Other/Not Reported	2.4%	5.8%

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VIEW 2

Baseline Disease Characteristics

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
n (full analysis set)	291	309	296	306
ETDRS BCVA (letter score ± SD)	54 ± 14	53 ± 14	52 ± 14	52 ± 14
Snellen Equivalent	20/80	20/100	20/100	20/100
Lesion Type: (%)				
Predominantly Classic	24.1%	23.3%	27.0%	28.8%
Minimally Classic	35.7%	36.2%	34.8%	34.6%
Occult no classic	39.9%	39.8%	38.2%	35.9%
Tot. Lesion Size (mm2, mean ± SD)	8.0 ± 5.7	8.7 ± 6.1	8.2 ± 5.5	8.2 ± 5.9
Central Retinal Thickness (µm ± SD)	326 ± 111	335 ± 120	327 ± 116	343 ± 124

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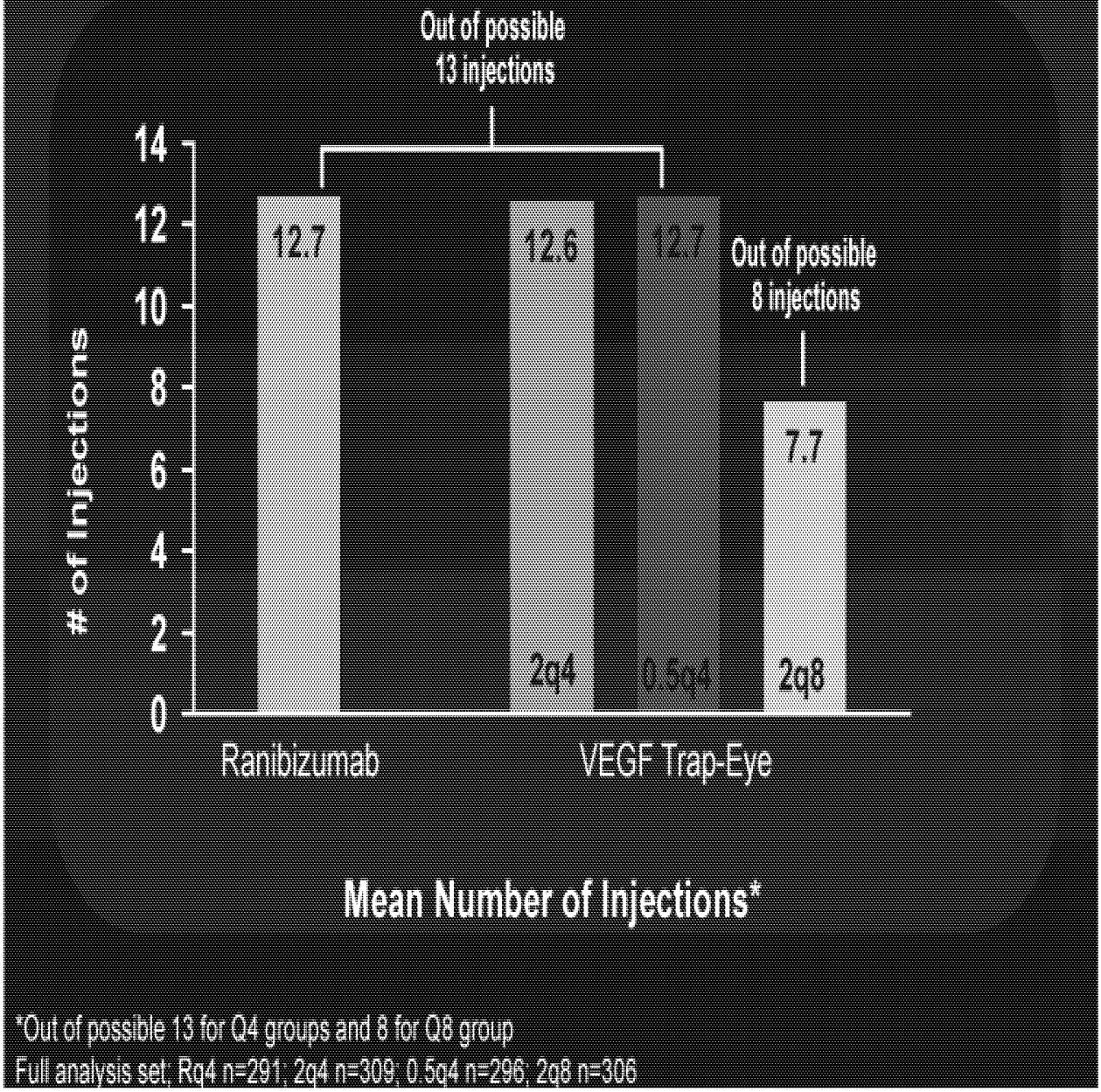
VIEW 1 & 2

Baseline Disease Characteristics

	VIEW 1 All Groups		VIEW 2 All Groups
n (full analysis set)	1210	n (full analysis set)	1202
ETDRS BCVA (letter score ± SD)	55 ± 13	ETDRS BCVA (letter score ± SD)	52 ± 14
Lesion Type: (%)		Lesion Type: (%)	
Predominantly Classic	26.5%	Predominantly Classic	25.8%
Minimally Classic	34.1%	Minimally Classic	35.4%
Occult no classic	38.3%	Occult no classic	38.4%
Lesion Size (mm^2, mean ± SD)	7.0 ± 5.2	Lesion Size (mm^2, mean ± SD)	8.3 ± 5.8
Total Retinal/ Lesion Thickness (µm ± SD)	487 ± 177	Central Retinal Thickness (µm ± SD)	333 ± 118

VIEW 2

Number of Active Injections Through 1 Year



Mean Number of Injections*

*Out of possible 13 for Q4 groups and 8 for Q8 group

Full analysis set: Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306

Visual Acuity

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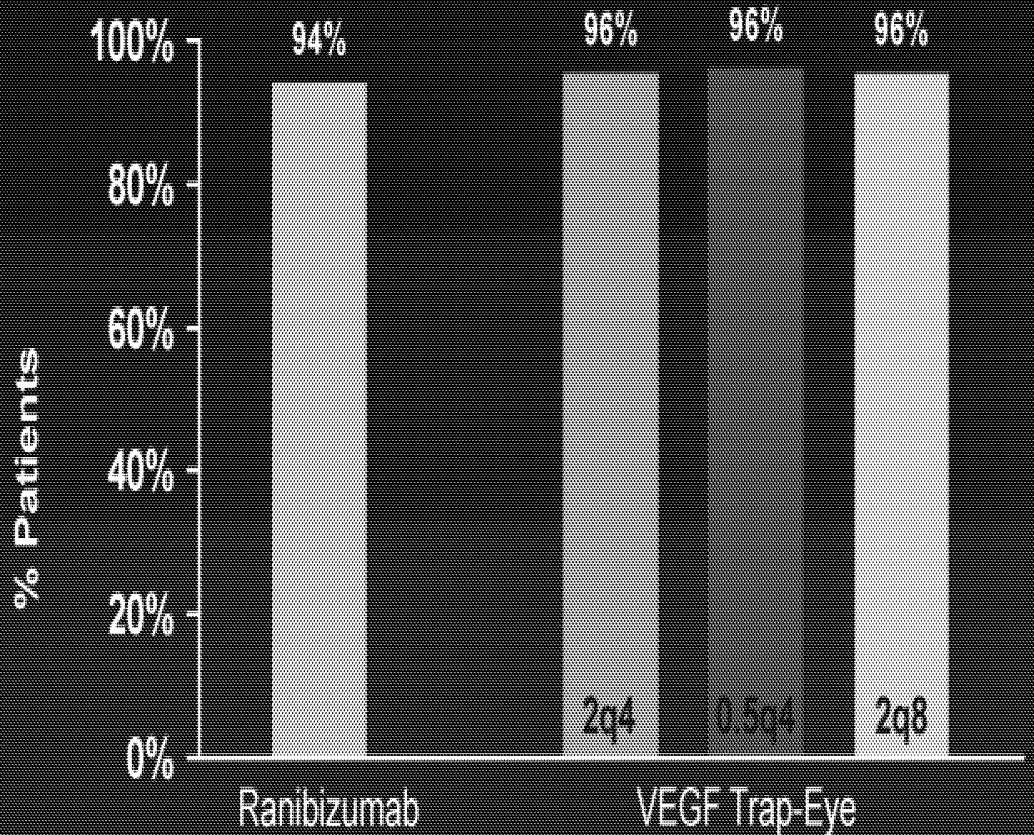
VIEW 2

Primary Endpoint: Prevention of Moderate Vision Loss

All doses of VEGF Trap-Eye were non-inferior to ranibizumab



<15 letter loss*

*Compared to baseline; LOCF; per protocol set: Rq4 n=269; 2q4 n=274; 0.5q4 n=268; 2q8 n=270

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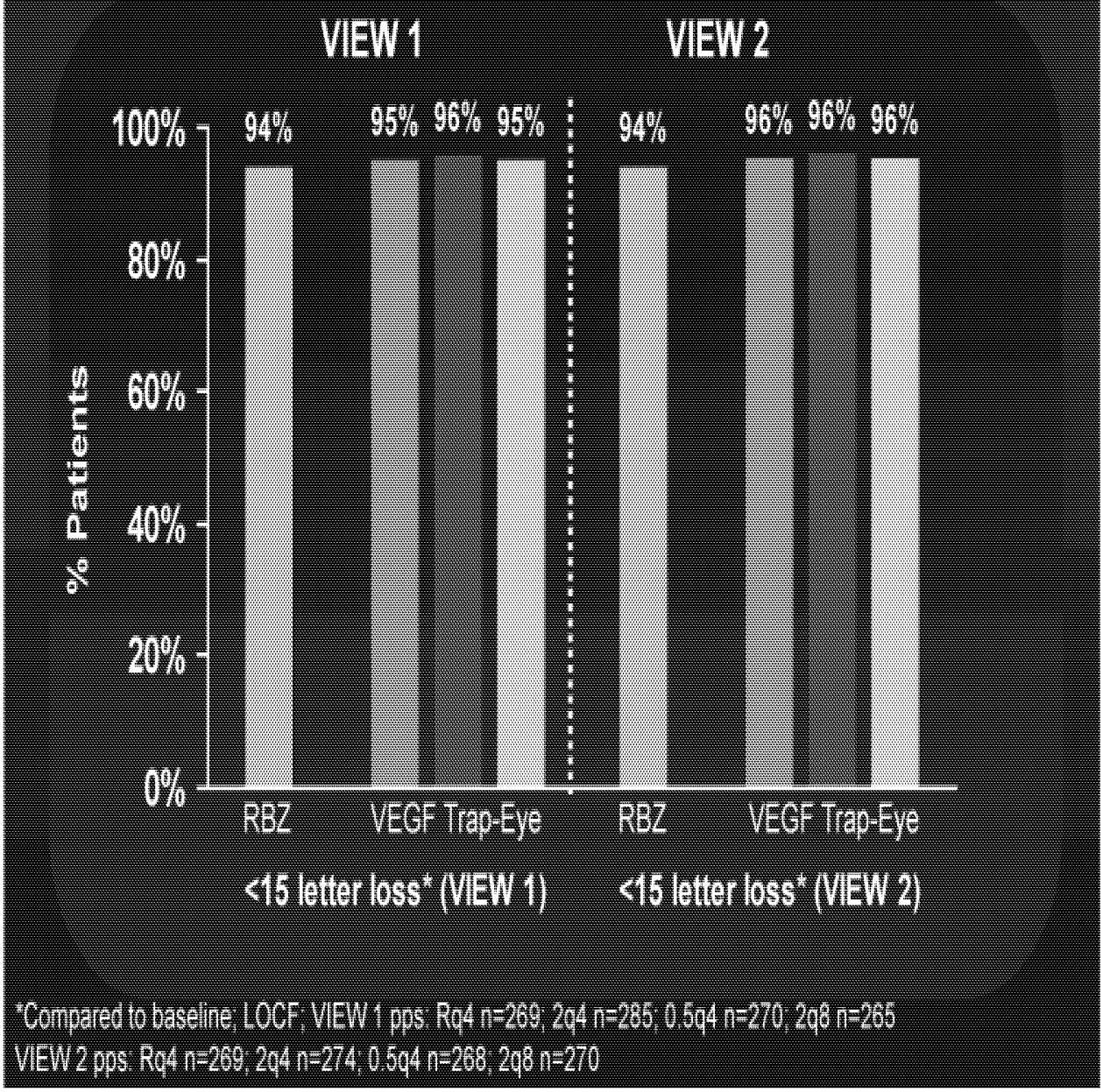
VIEW 1 & 2

Primary Endpoint: Prevention of Moderate Vision Loss



*Compared to baseline; LOCF; VIEW 1 pps: Rq4 n=269; 2q4 n=285; 0.5q4 n=270; 2q8 n=265
VIEW 2 pps: Rq4 n=269; 2q4 n=274; 0.5q4 n=268; 2q8 n=270

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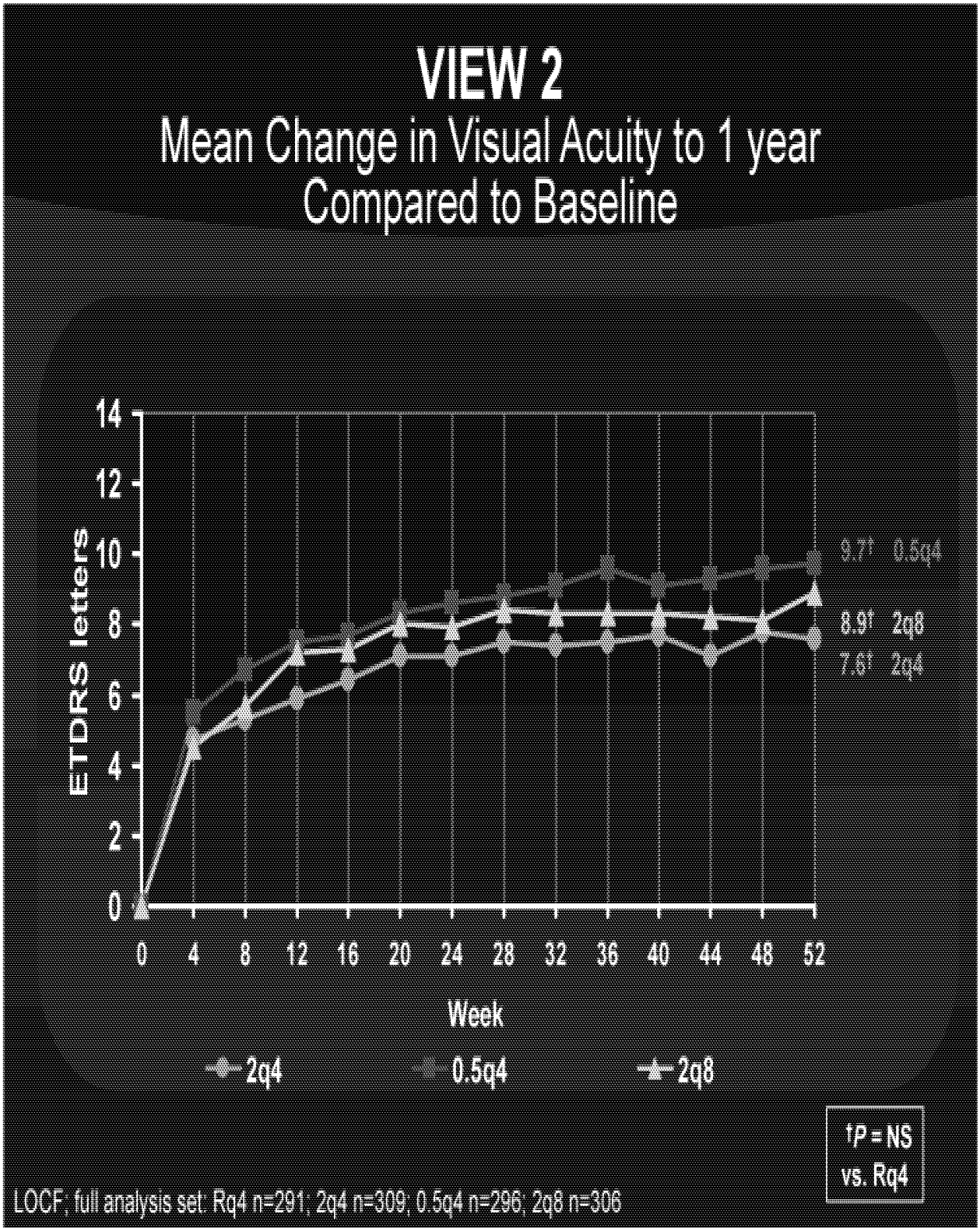
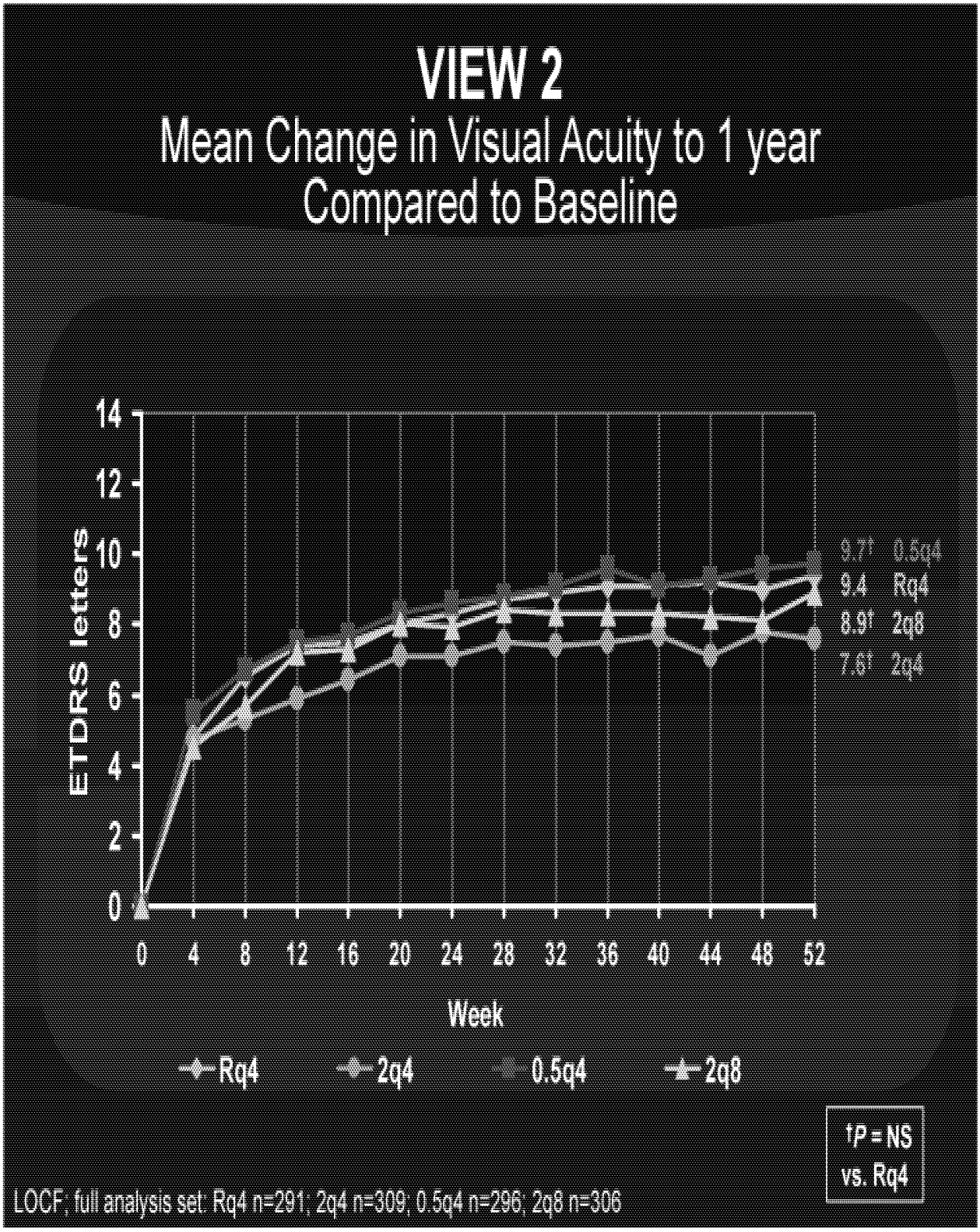
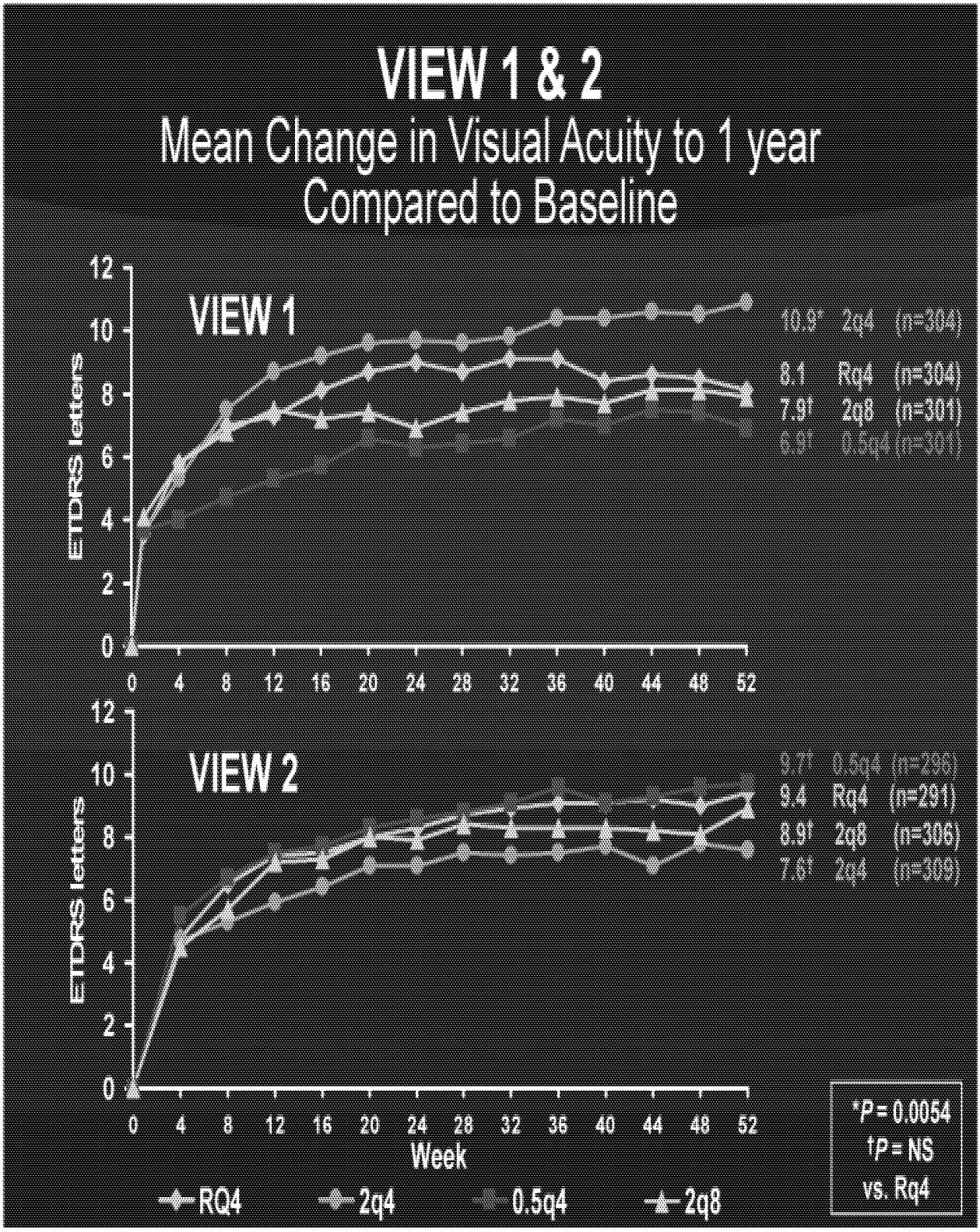
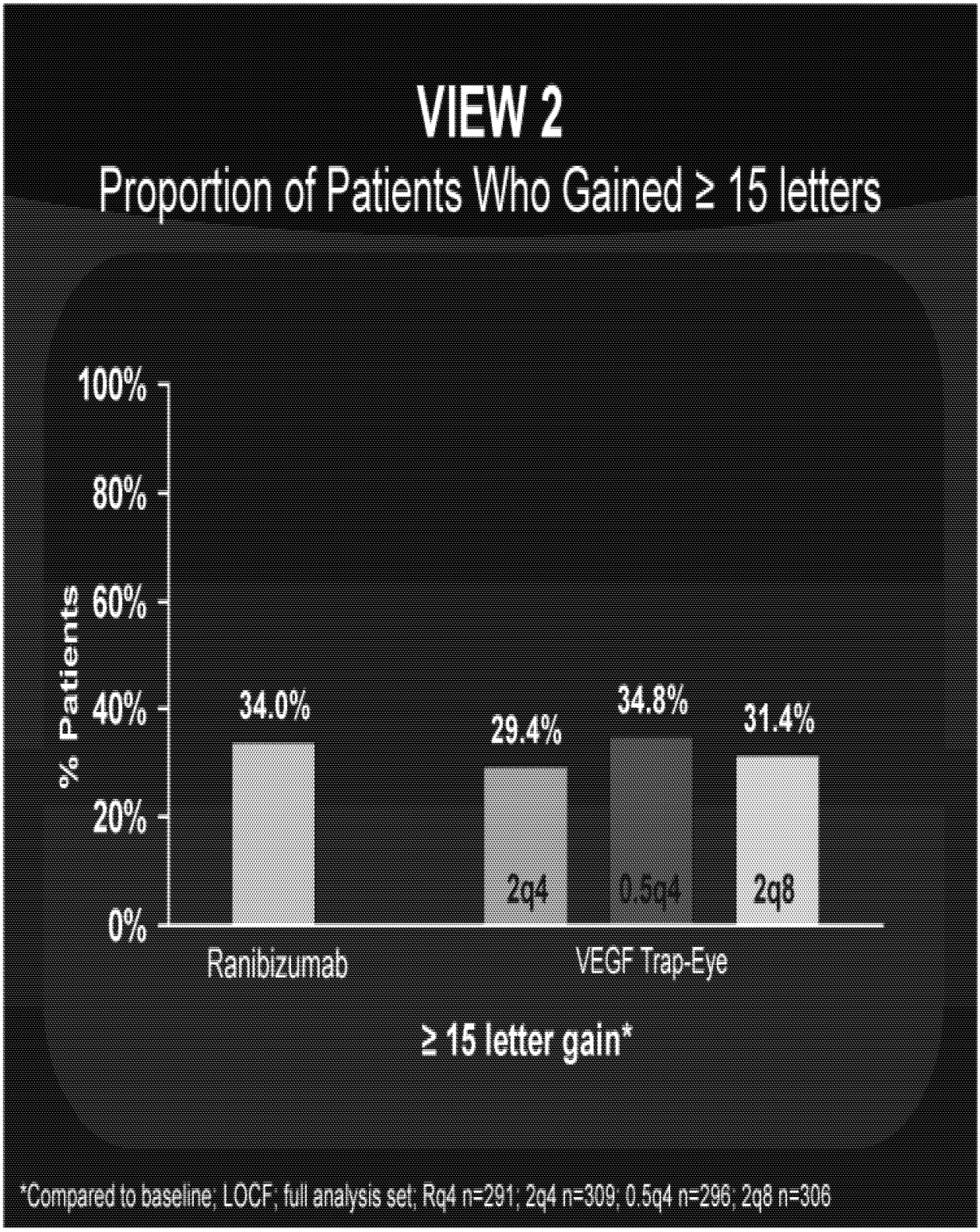
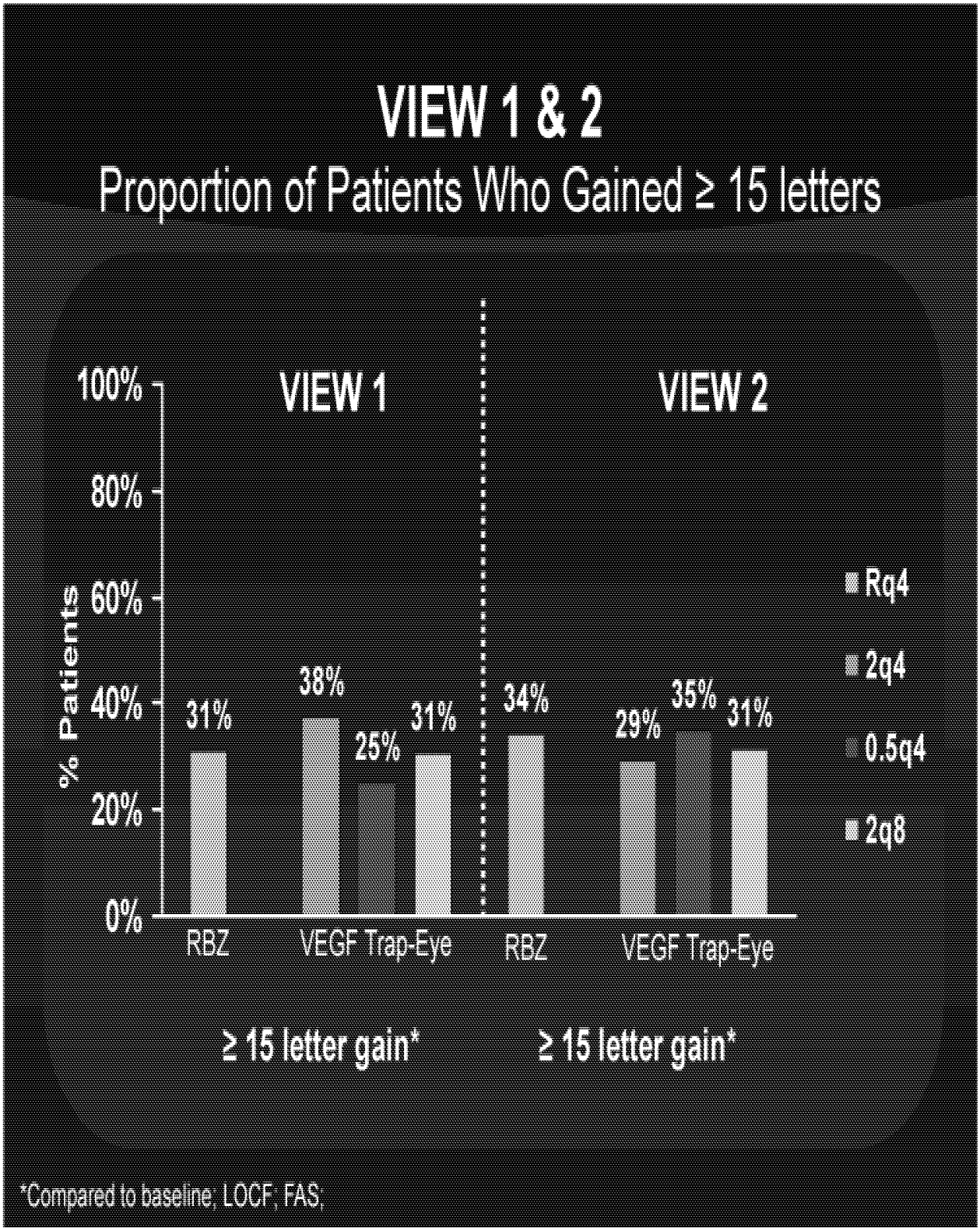
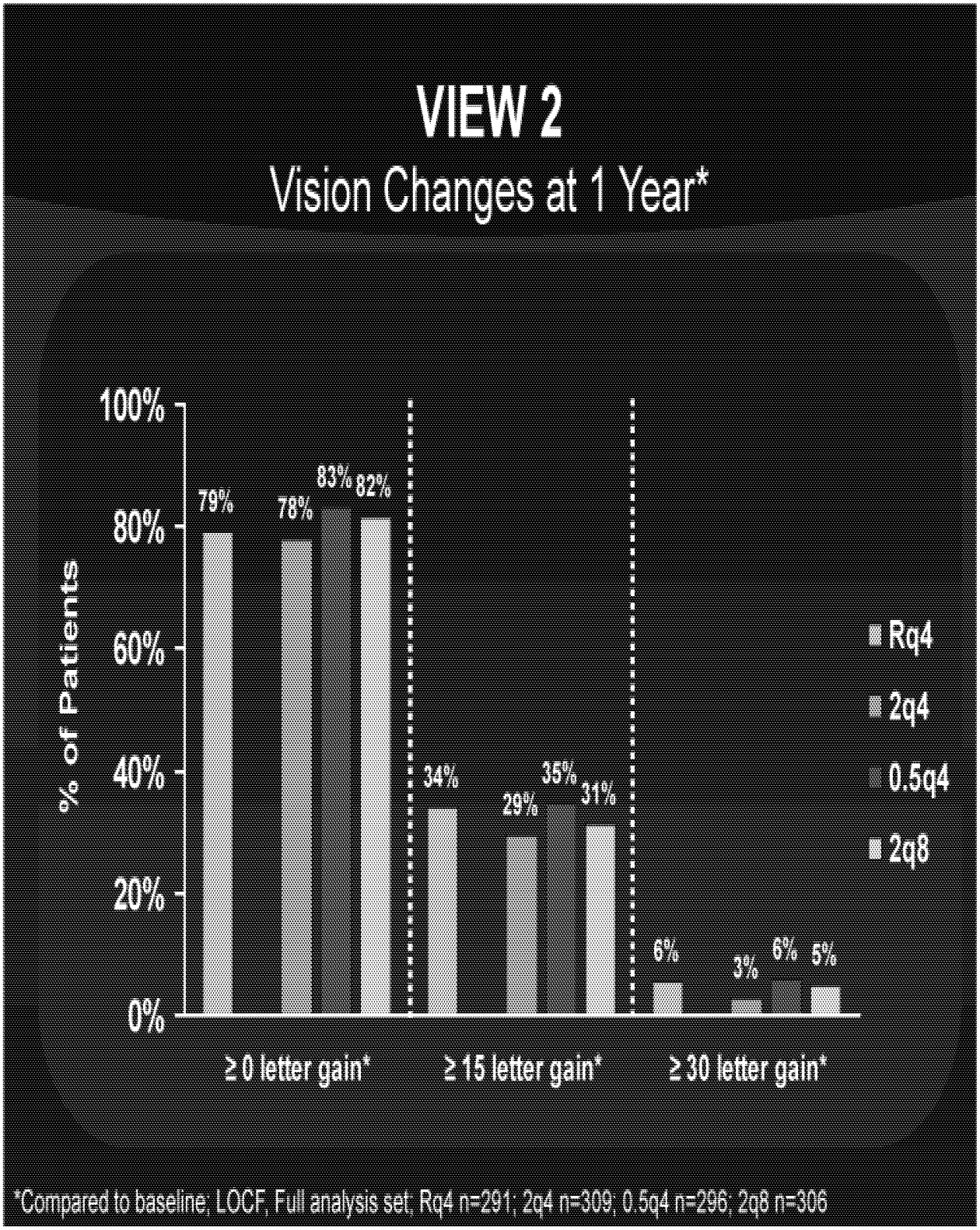

VIEW 2
Mean Change in Visual Acuity to 1 year
Compared to Baseline
ETDRS letters
14
12
10
8
6
4
2
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Week
9.7† 0.5q4
8.9† 2q8
7.6† 2q4
2q4
0.5q4
2q8
†P = NS
vs. Rq4
LOCF; full analysis set: Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306

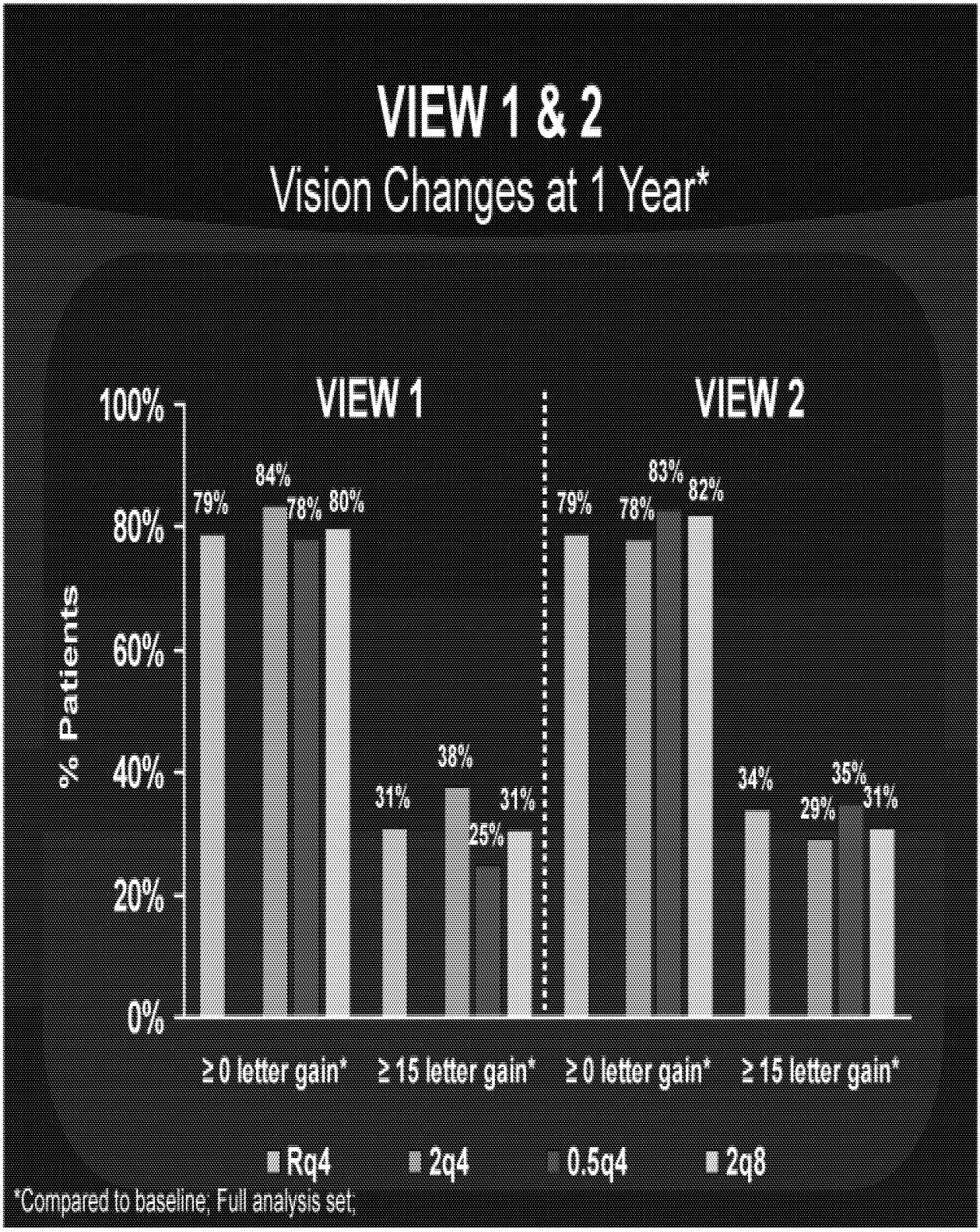

VIEW 2
Mean Change in Visual Acuity to 1 year
Compared to Baseline
ETDRS letters
14
12
10
8
6
4
2
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Week
9.7† 0.5q4
9.4 Rq4
8.9† 2q8
7.6† 2q4
Rq4
2q4
0.5q4
2q8
†P = NS vs. Rq4
LOCF; full analysis set: Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306

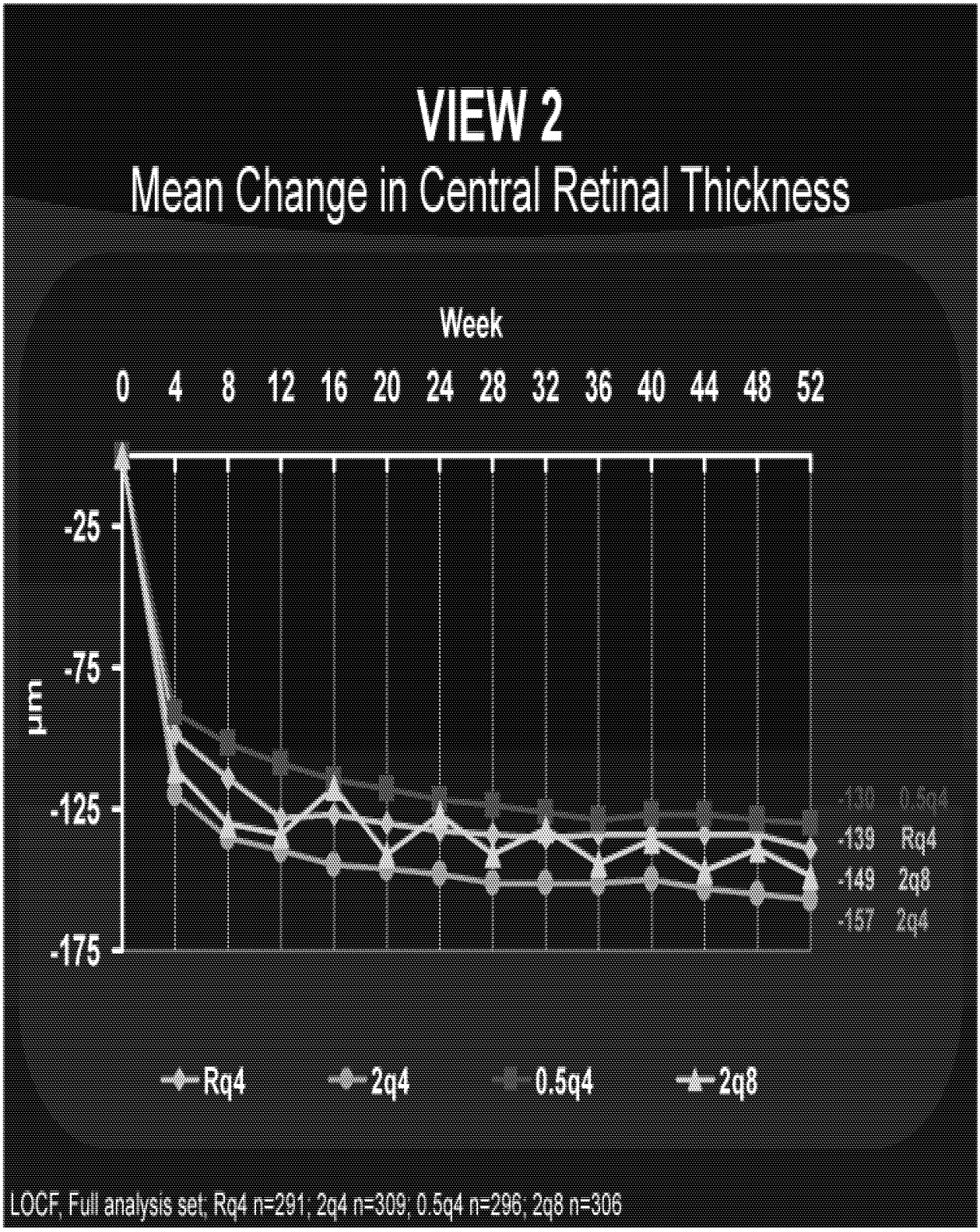

VIEW 1 & 2
Mean Change in Visual Acuity to 1 year
Compared to Baseline
VIEW 1
VIEW 2
ETDRS letters
Week
10.9* 2q4 (n=304)
8.1 Rq4 (n=304)
7.9† 2q8 (n=301)
6.9† 0.5q4 (n=301)
9.7† 0.5q4 (n=296)
9.4 Rq4 (n=291)
8.9† 2q8 (n=306)
7.6† 2q4 (n=309)
*P = 0.0054
†P = NS
vs. Rq4
RQ4
2q4
0.5q4
2q8

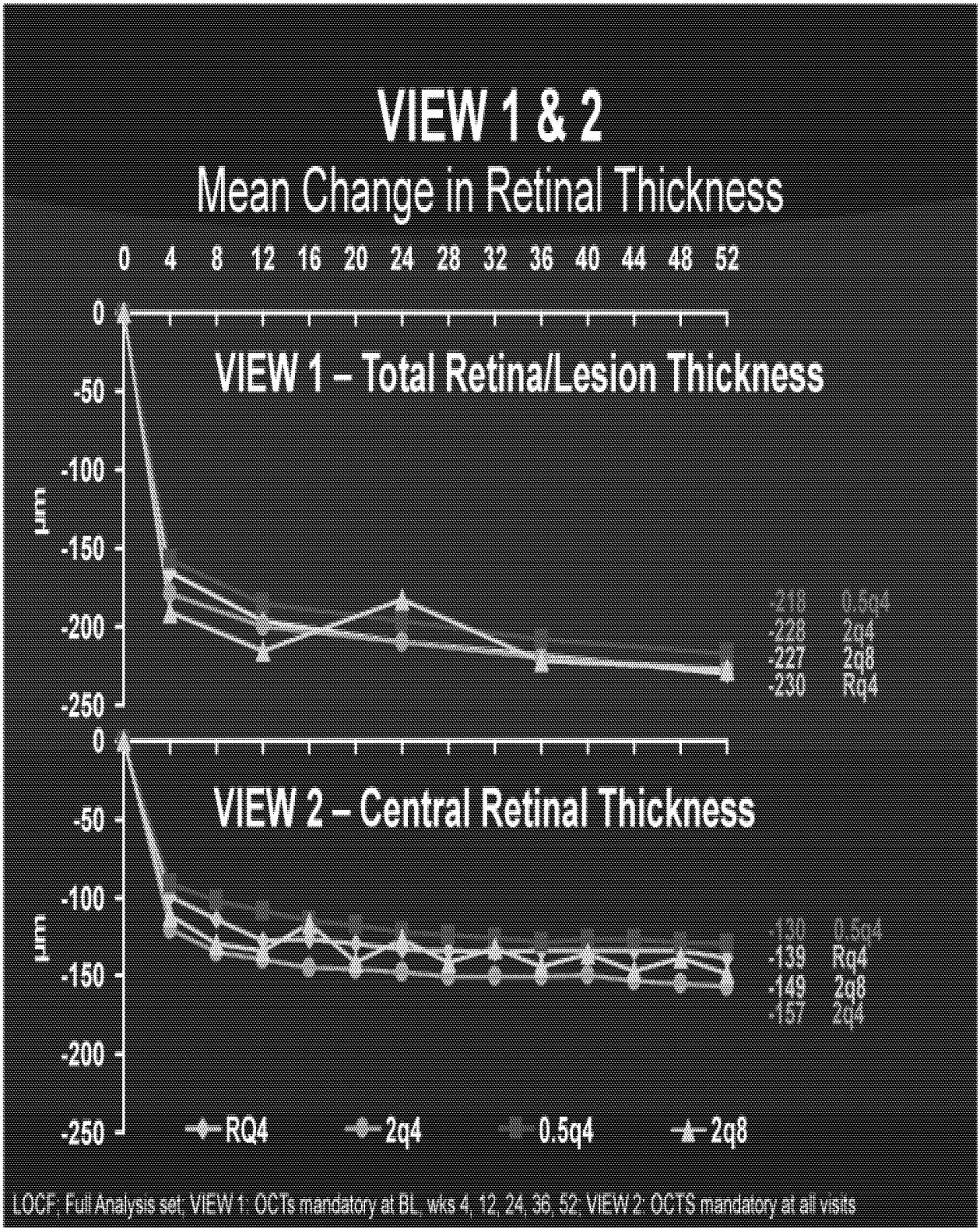

VIEW 2
Proportion of Patients Who Gained ≥ 15 letters
100%
80%
60%
40%
20%
0%
% Patients
34.0%
29.4%
34.8%
31.4%
2q4
0.5q4
2q8
Ranibizumab
VEGF Trap-Eye
≥ 15 letter gain*
*Compared to baseline; LOCF; full analysis set; Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306


VIEW 1 & 2
Proportion of Patients Who Gained ≥ 15 letters
VIEW 1
VIEW 2
% Patients
100%
80%
60%
40%
20%
0%
31%
38%
25%
31%
34%
29%
35%
31%
RBZ
VEGF Trap-Eye
RBZ
VEGF Trap-Eye
Rq4
2q4
0.5q4
2q8
≥ 15 letter gain*
≥ 15 letter gain*
*Compared to baseline; LOCF; FAS;


VIEW 2
Vision Changes at 1 Year*
% of Patients
100%
80%
60%
40%
20%
0%
79%
78%
83%
82%
34%
29%
35%
31%
6%
3%
6%
5%
Rq4
2q4
0.5q4
2q8
≥ 0 letter gain*
≥ 15 letter gain*
≥ 30 letter gain*
*Compared to baseline; LOCF, Full analysis set; Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306


VIEW 1 & 2
Vision Changes at 1 Year*
VIEW 1
VIEW 2
% Patients
100%
80%
60%
40%
20%
0%
79%
84%
78%
80%
31%
38%
25%
31%
79%
78%
83%
82%
34%
29%
35%
31%
≥ 0 letter gain*
≥ 15 letter gain*
≥ 0 letter gain*
≥ 15 letter gain*
Rq4
2q4
0.5q4
2q8
*Compared to baseline; Full analysis set;


VIEW 2
Mean Change in Central Retinal Thickness
Week
0 4 8 12 16 20 24 28 32 36 40 44 48 52
-25
-75
-125
-175
µm
-139 Rq4
-149 2q8
-157 2q4
Rq4
2q4
0.5q4
2q8
LOCF, Full analysis set; Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306


VIEW 1 & 2
Mean Change in Retinal Thickness
0 4 8 12 16 20 24 28 32 36 40 44 48 52
VIEW 1 – Total Retina/Lesion Thickness
μm
0
-50
-100
-150
-200
-250
-218 0.5q4
-228 2q4
-227 2q8
-230 Rq4
VIEW 2 – Central Retinal Thickness
μm
-130 0.5q4
-139 Rq4
-149 2q8
-157 2q4
RQ4
2q4
0.5q4
2q8
LOCF; Full Analysis set; VIEW 1: OCTs mandatory at BL, wks 4, 12, 24, 36, 52; VIEW 2: OCTS mandatory at all visits

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VIEW 2

Patients with Study Eye Ocular Serious Adverse Events

	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
n (safety analysis set)	291	309	297	307	913
# of subjects with at least 1 AE	9 (3.1%)	7 (2.3%)	5 (1.7%)	9 (2.9%)	21 (2.3%)
Endophthalmitis	0	0	0	0	0
Visual acuity reduced	1 (0.3%)	1 (0.3%)	1 (0.3%)	4 (1.3%)	6 (0.7%)
Retinal haemorrhage	1 (0.3%)	2 (0.6%)	1 (0.3%)	1 (0.3%)	4 (0.4%)
Macular degeneration	0	1 (0.3%)	0	1 (0.3%)	2 (0.2%)
Intraocular pressure increased	0	0	1 (0.3%)	1 (0.3%)	2 (0.2%)
Cataract	1 (0.3%)	1 (0.3%)	0	1 (0.3%)	2 (0.2%)
Retinal pigment epithelial tear	1 (0.3%)	0	1 (0.3%)	1 (0.3%)	2 (0.2%)
Cataract nuclear	0	1 (0.3%)	0	0	1 (0.1%)
Choroidal detachment	0	0	0	1 (0.3%)	1 (0.1%)
Macular cyst	0	0	0	1 (0.3%)	1 (0.1%)
Macular hole	0	0	1 (0.3%)	0	1 (0.1%)
Macular scar	0	1 (0.3%)	0	0	1 (0.1%)
Retinal detachment	1 (0.3%)	0	1 (0.3%)	0	1 (0.1%)
Retinal pigment epitheliopathy	0	1 (0.3%)	0	0	1 (0.1%)
Cataract cortical	1 (0.3%)	0	0	0	0
Posterior capsule opacification	2 (0.7%)	0	0	0	0
Retinal degeneration	1 (0.3%)	0	0	0	0
Hyphaema	1 (0.3%)	0	0	0	0

VIEW 2

Deaths

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
N (safety analysis set)	291	309	297	307	913
All Deaths*	2 (0.7%)	3 (1.0%)	2 (0.7%)	2 (0.7%)	7 (0.8%)
Myocardial Infarction	1	1*	1	0	2
Cerebrovascular Accident	0	1*	0	0	1
Pyrexia	0	1	0	0	1
Cardiopulmonary Failure	0	1	0	0	1
Cancer Related	1	0	0	1	1
Cardiac Arrest	0	0	0	1	1
Unknown	0	0	1	0	1

* One patient experienced 2 events leading to death

VIEW 2

Patients with APTC Events through 1 Year

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
N (safety analysis set)	291	309	297	307	913
Any APTC event	5 (1.7%)	4 (1.3%)	5 (1.7%)	8 (2.6%)	17 (1.9%)
Vascular Deaths	1 (0.3%)	1 (0.3%)	2 (0.7%)	1 (0.3%)	4 (0.4%)
Non Fatal MI	2 (0.7%)	2 (0.6%)	2 (0.7%)	5 (1.6%)	9 (1.0%)
Non Fatal Stroke[b]	2 (0.7%)	1 (0.3%)	1 (0.3%)	2 (0.7%)	4 (0.4%)

Note: Percentage values (rounded to one decimal place) were calculated by author

[b]Non-fatal hemorrhagic and ischemic strokes were combined to one category

VIEW 1 & 2

% Patients with APTC Events through 1 Year

VIEW 1

	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
N (safety analysis set)	304	304	304	303	911
Any APTC event	5 (1.6)	2 (0.7)	7 (2.3)	6 (2.0)	15 (1.6)
Vascular Deaths	1 (0.3)	0	1 (0.3)	4 (1.3)	5 (0.5)
Non Fatal MI	4 (1.3)	1 (0.3)	4 (1.3)	1 (0.3)	6 (0.7)
Non Fatal Stroke[a]	0	1 (0.3)	2 (0.7)	1 (0.3)	4 (0.4)

VIEW 2

	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
N (safety analysis set)	291	309	297	307	913
Any APTC event	5 (1.7)	4 (1.3)	5 (1.7)	8 (2.6)	17 (1.9)
Vascular Deaths	1 (0.3)	1 (0.3)	2 (0.7)	1 (0.3)	4 (0.4)
Non Fatal MI	2 (0.7)	2 (0.6)	2 (0.7)	5 (1.6)	9 (1.0)
Non Fatal Stroke[b]	2 (0.7)	1 (0.3)	1 (0.3)	2 (0.7)	4 (0.4)

[a]All non fatal strokes were ischemic in nature

[b]Includes hemorrhagic and ischemic strokes

VIEW 1 & 2
Hypertension

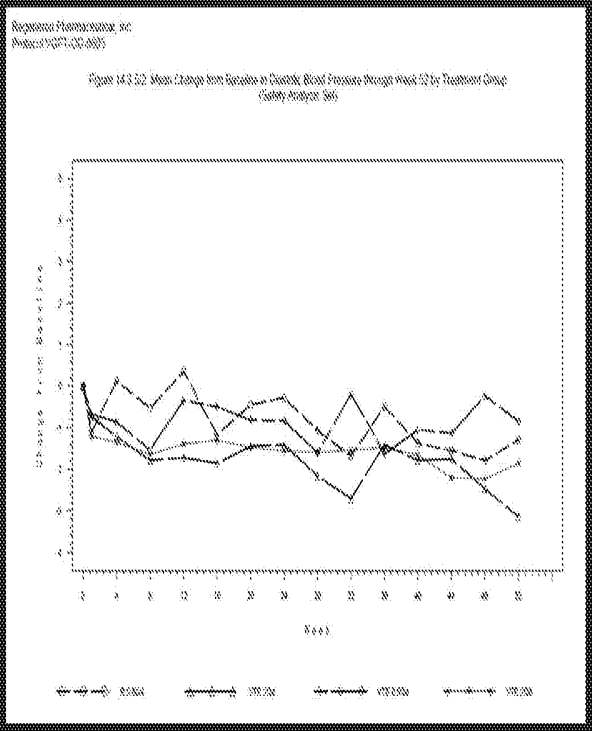
VIEW 1

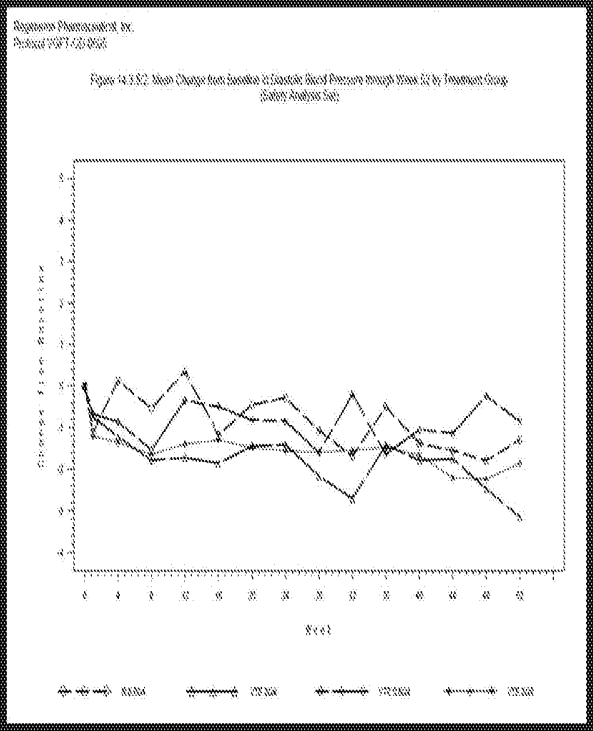
	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
N (safety analysis set)	304	304	304	303	911
# with at least 1 Hypertension AE	29 (9.5%)	25 (8.2%)	26 (8.6%)	31 (10.2%)	82 (9.0%)

VIEW 2

	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
N (safety analysis set)	291	309	297	307	913
# with at least 1 Hypertension AE	29 (10.0%)	31 (10.0%)	22 (7.4%)	28 (9.1%)	81 (8.9%)

Mean change in blood pressure over 12 months





systolic

diastolic

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VIEW 1 & 2

Conclusion: Efficacy

- Results with all VEGF Trap-Eye regimens were shown to be statistically non-inferior with clinically equivalent outcomes to monthly ranibizumab treatment in two independent trials

- The regimen applying 2 mg VEGF Trap-Eye at every two month intervals following a loading dose demonstrated similar functional and anatomical efficacy compared to monthly ranibizumab

VIEW 1 & 2

Conclusion: Safety

- All VEGF Trap-Eye treatment arms in both studies demonstrated a favorable safety profile in a typical AMD population
- VTE was generally safe and well-tolerated without differences compared to monthly ranibizumab in ocular and non-ocular AEs
- No endophthalmitis was reported in VIEW 2
- APTC-defined ATE events were rare and similar among the groups
  - Vascular deaths occurred < 1 %

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Conclusions

With the introduction of VEGF Trap-Eye
another important step is taken
in the treatment of neovascular AMD
in respect to

- Efficacy
- Practicality
- Multi-ethnicity

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VEGF Trap – Eye
CLEAR-IT 2 Final Primary Endpoint Results

A Phase 2, Randomized, Controlled Dose- and Interval-Ranging Study of Intravitreal VEGF Trap-Eye in Patients with Neovascular Age-Related Macular Degeneration

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Disclosures

- Commercial relationships
  - J. Heier, Regeneron financial support
- Trial registration
  - www.clinicaltrials.gov (NCT00320788)

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Angiogenesis Inhibition via VEGF Blockade Unmet Medical Needs Remain Despite Major Advances in Treatment of Wet AMD

- Ranibizumab (LUCENTIS®*) represents a major advance in wet AMD treatment
  - The approved regimen of ranibizumab in the U.S., 0.5 mg administered monthly, resulted in the following results at 1 year:[1]
    - Prevention of moderate vision loss in 95-96% of patients
    - A ≥15 letter (3-line) gain in 34- 40% of patients
    - Mean improvement in visual acuity of 7.2-11.3 letters (~6-10 at month 4)
    - Vision of ≥20/40 in 39-40% of patients
    - Vision of ≤20/200 in only 12-16% of patients
- A clinical need remains for an agent that can further improve vision
  - Further improvement in visual acuity
  - More patients with vision of ≥20/40
  - Fewer patients with vision of ≤20/200
- A clinical need remains for an agent that improves and maintains visual acuity with a dosing schedule requiring less than monthly injections

* LUCENTIS® is a registered trademark of GENENTECH, Inc

1 Rosenfeld, et al., *N Engl. J Med.*, 2006 355(14):1419-31; Brown, et al., *N Engl. J Med.*, 2006 355(14): 1432-44

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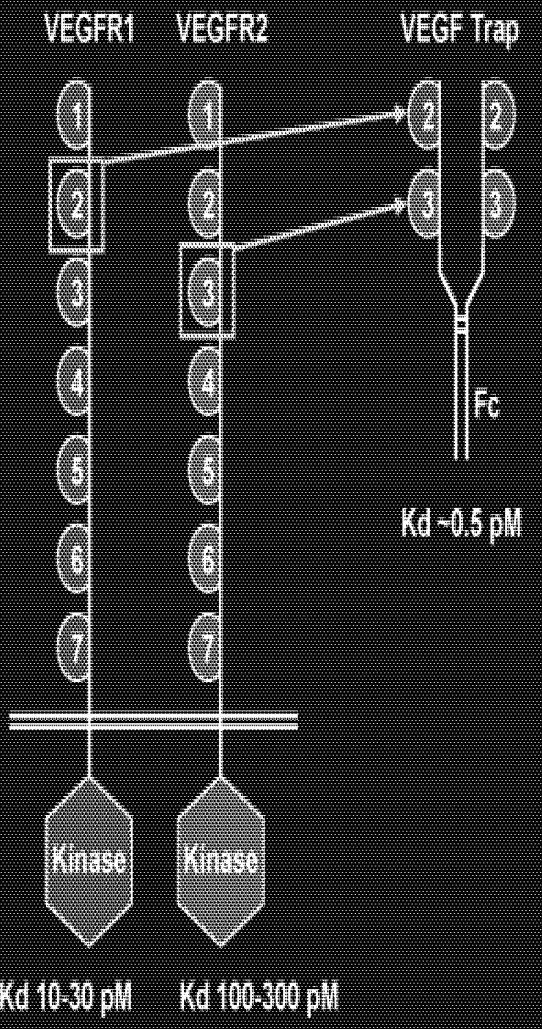
VEGF Trap-Eye*: A Unique VEGF Blocker



- Fusion protein of key domains from human VEGF receptors 1 and 2 with human IgG Fc
- Contains all human amino acid sequences
- High affinity and binds VEGF more tightly than native receptors or monoclonal antibody
- Blocks all VEGF-A isoforms and Placental Growth Factor (PlGF)
- Penetrates all layers of the retina (MW ~110,000)

*VEGF Trap–Eye is specially purified and formulated for intravitreal injection.
IgG=immunoglobulin G; MW=molecular weight; VEGF=vascular endothelial growth factor; VEGFR=vascular endothelial growth factor receptor.

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CLEAR-IT 2 Study Objectives

- Primary objectives:
  - Assess the effect of intravitreal VEGF Trap-Eye on retinal thickness
  - Assess ocular and systemic safety and tolerability of repeated IVT doses of VEGF Trap-Eye in wet AMD
- Secondary objective:
  - Assess the effect of IVT VEGF Trap-Eye on best-corrected visual acuity in ETDRS letters

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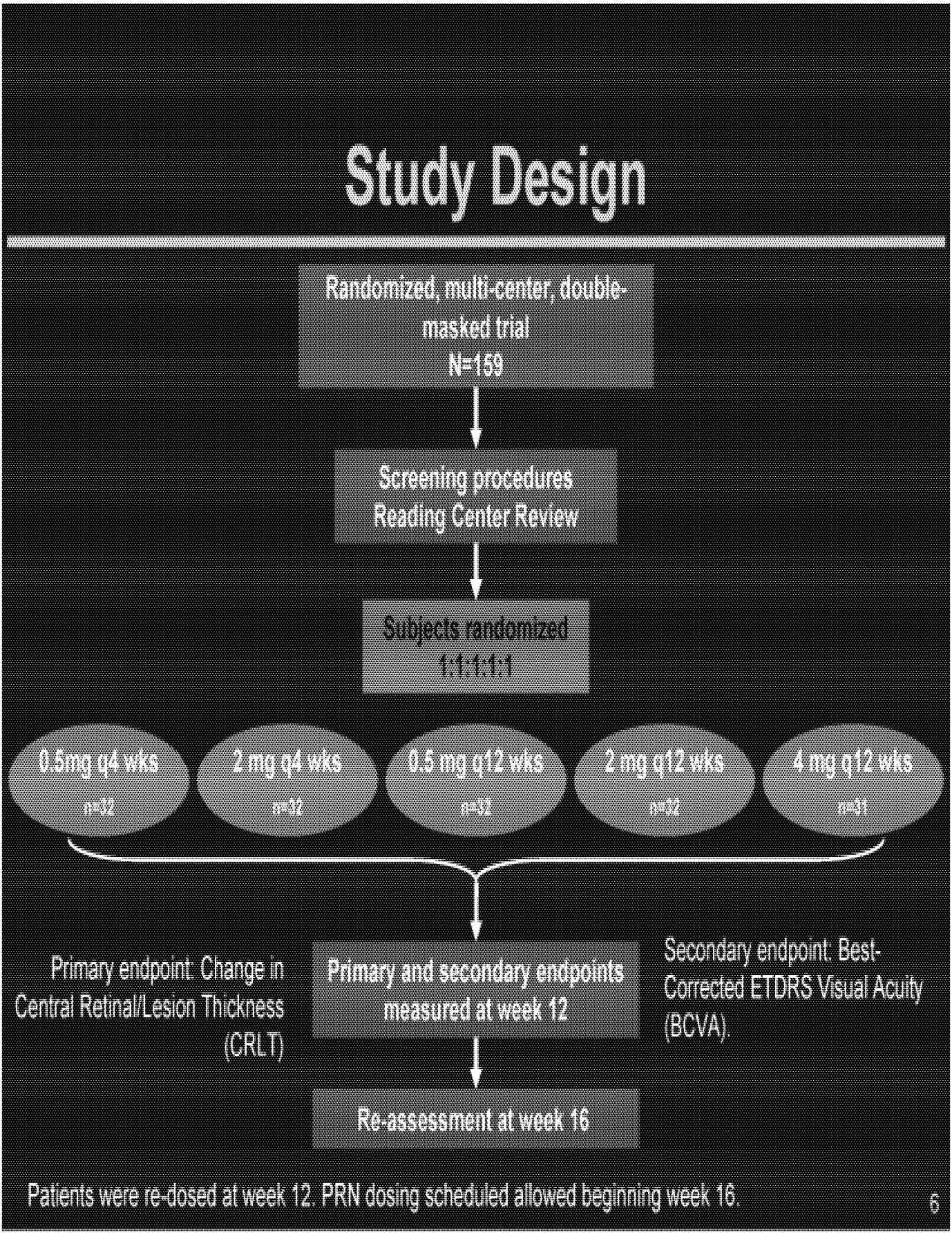
Study Design



Patients were re-dosed at week 12. PRN dosing scheduled allowed beginning week 16.

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Baseline Characteristics

(N=157*)	Mean	Range
Age (years)	78.2	53-94
Gender (%M:%F)	38:62	
Disease Duration (months)	3.9	0-67
Lesion Type: number (%)		
Classic	30 (19.1)	
Predominantly Classic	30 (19.1)	
Minimally Classic	37 (23.6)	
Occult Lesions	60 (38.2)	
Disease Status		
Central Retinal/Lesion Thickness	456µm	186-1316µm
Foveal Thickness	327µm	116-1081µm
ETDRS BCVA (Letters)	56	27-83

*N=159 randomized; N=157 treated.

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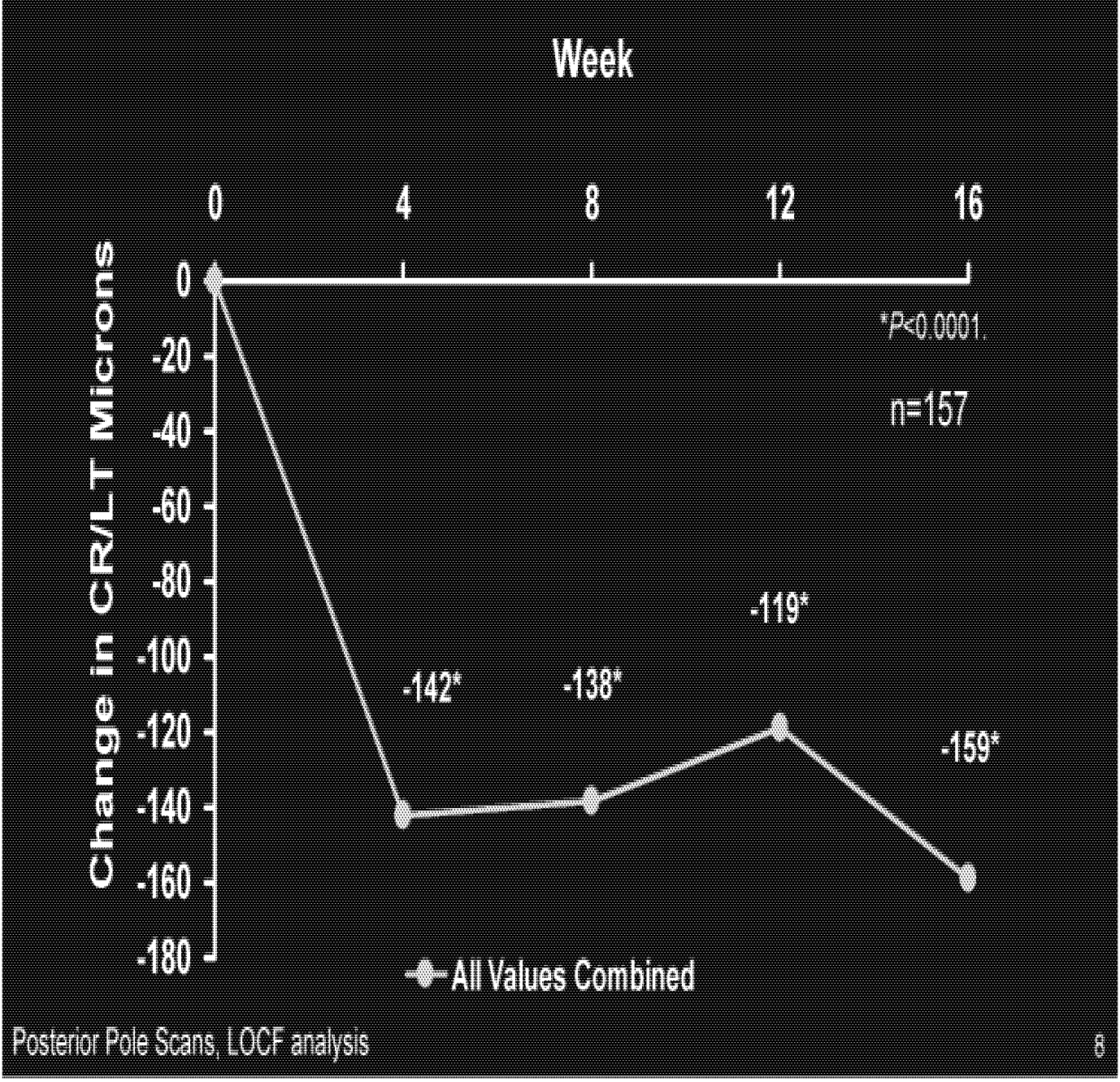
Mean Change in Central Retinal Thickness: Significantly Improved vs Baseline at All Time Points



Posterior Pole Scans, LOCF analysis

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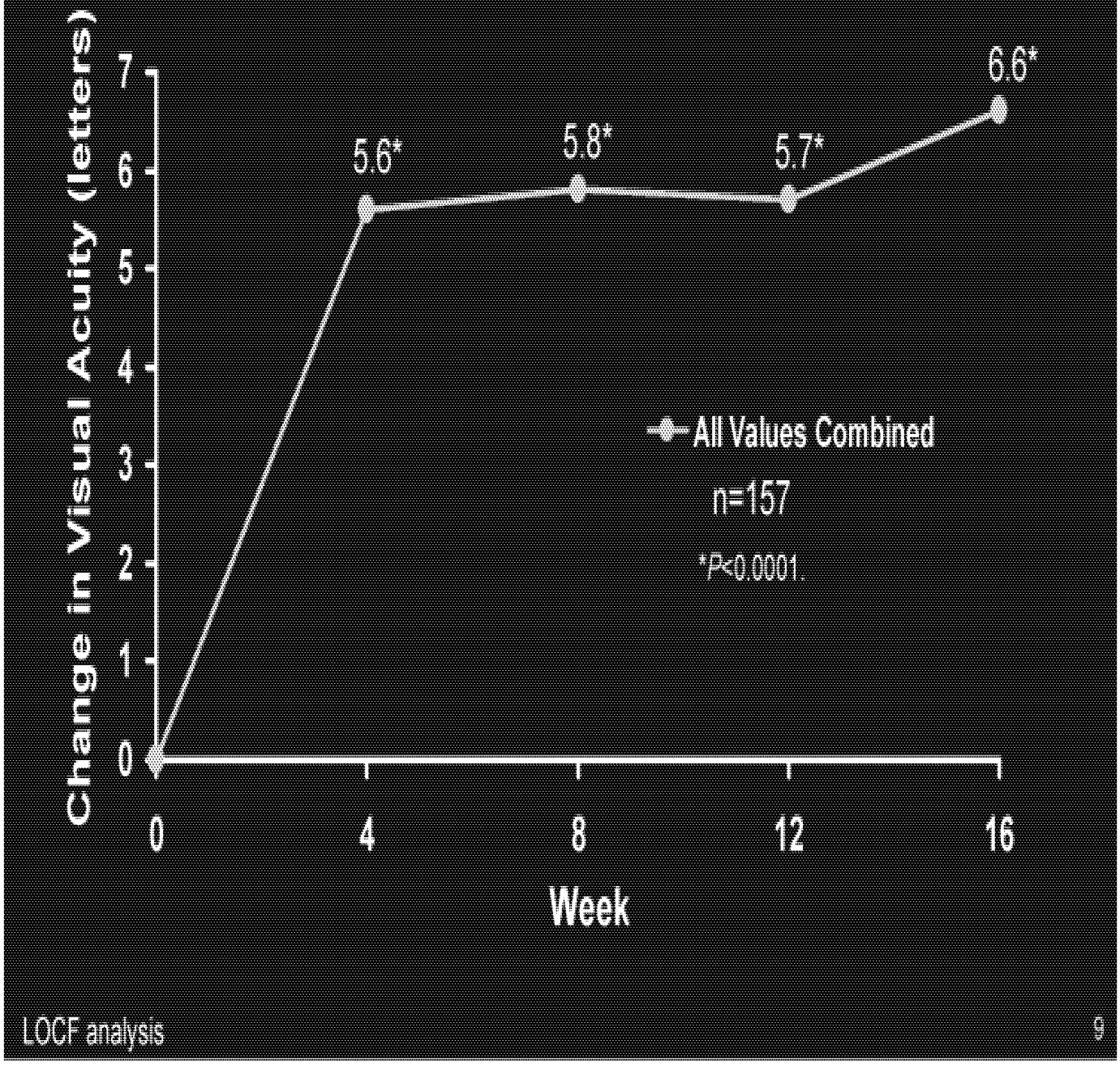
Mean Change in Visual Acuity: Significantly Improved vs Baseline at All Time Points



LOCF analysis

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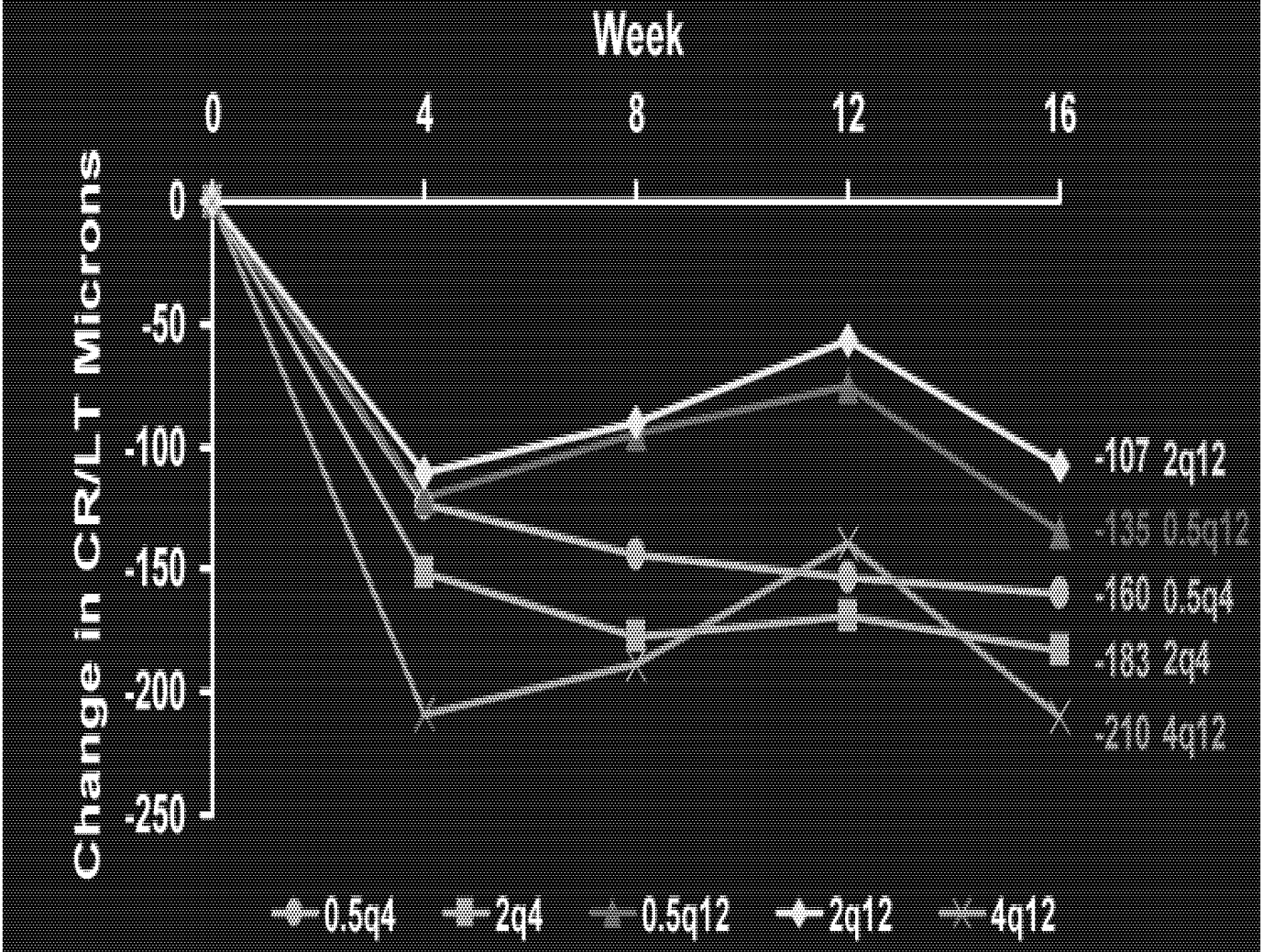
Mean Change in Retinal Thickness: Improved in All Dosing Arms; Monthly Dosing More Consistent in Effect



Posterior Pole Scans, LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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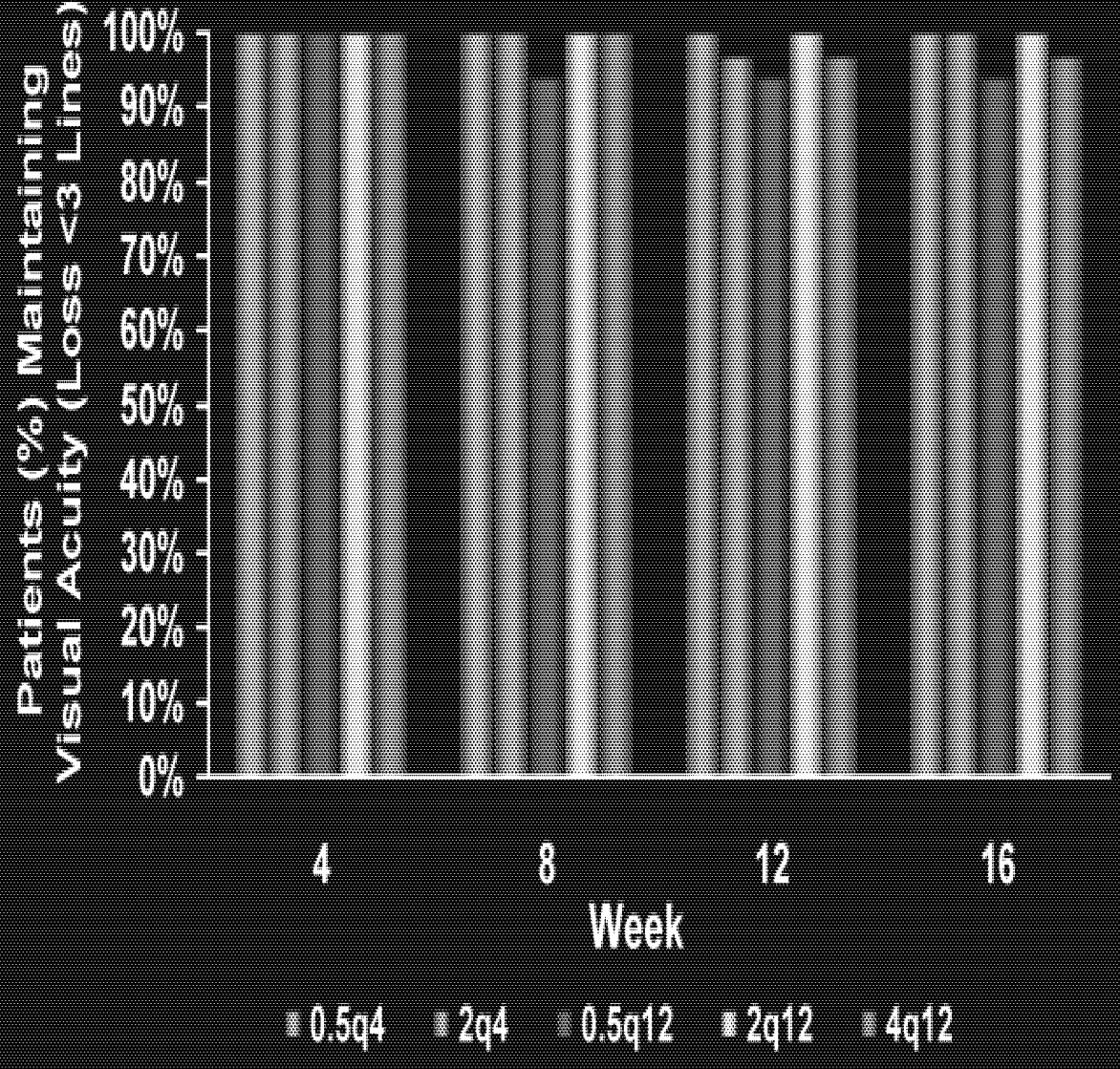
Maintenance of Visual Acuity: Maintained in All Dosing Arms



LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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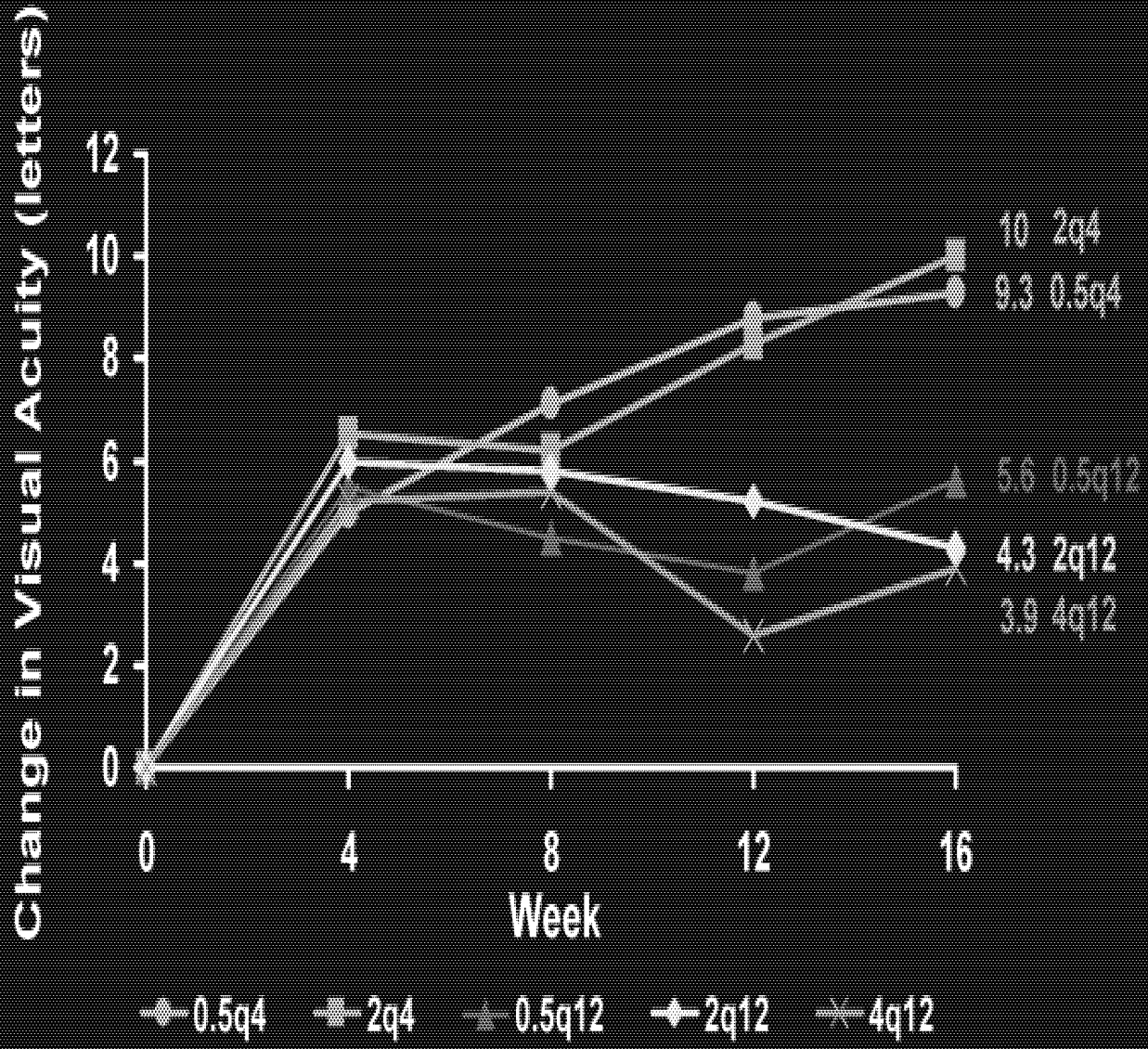
Mean Change in Visual Acuity: Improved in All Dosing Arms; Monthly Dosing Continued to Improve Vision out to Week 16



LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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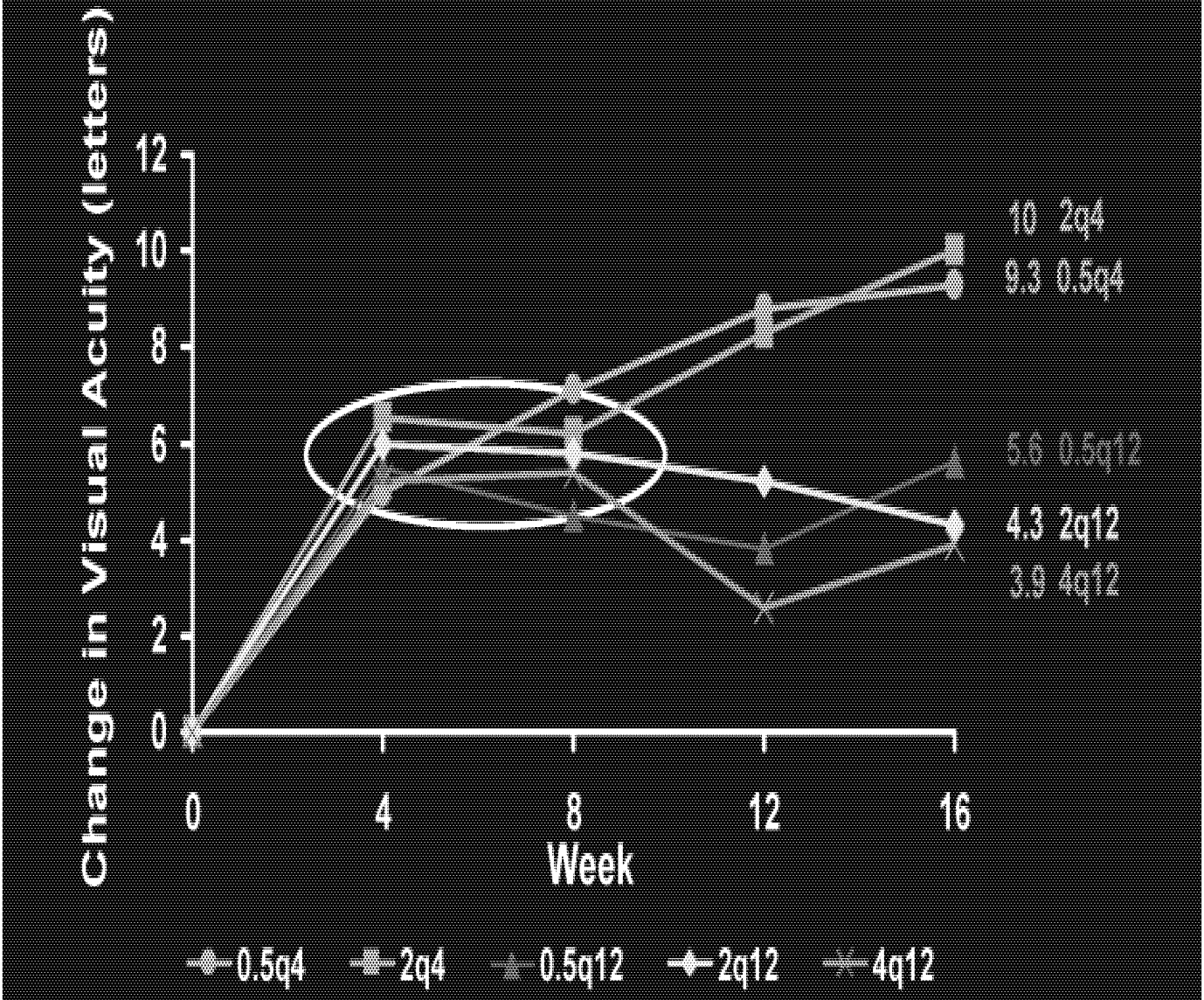
Mean Change in Visual Acuity: Maintained at 8 Weeks With a Single Dose, and With Monthly Dosing



LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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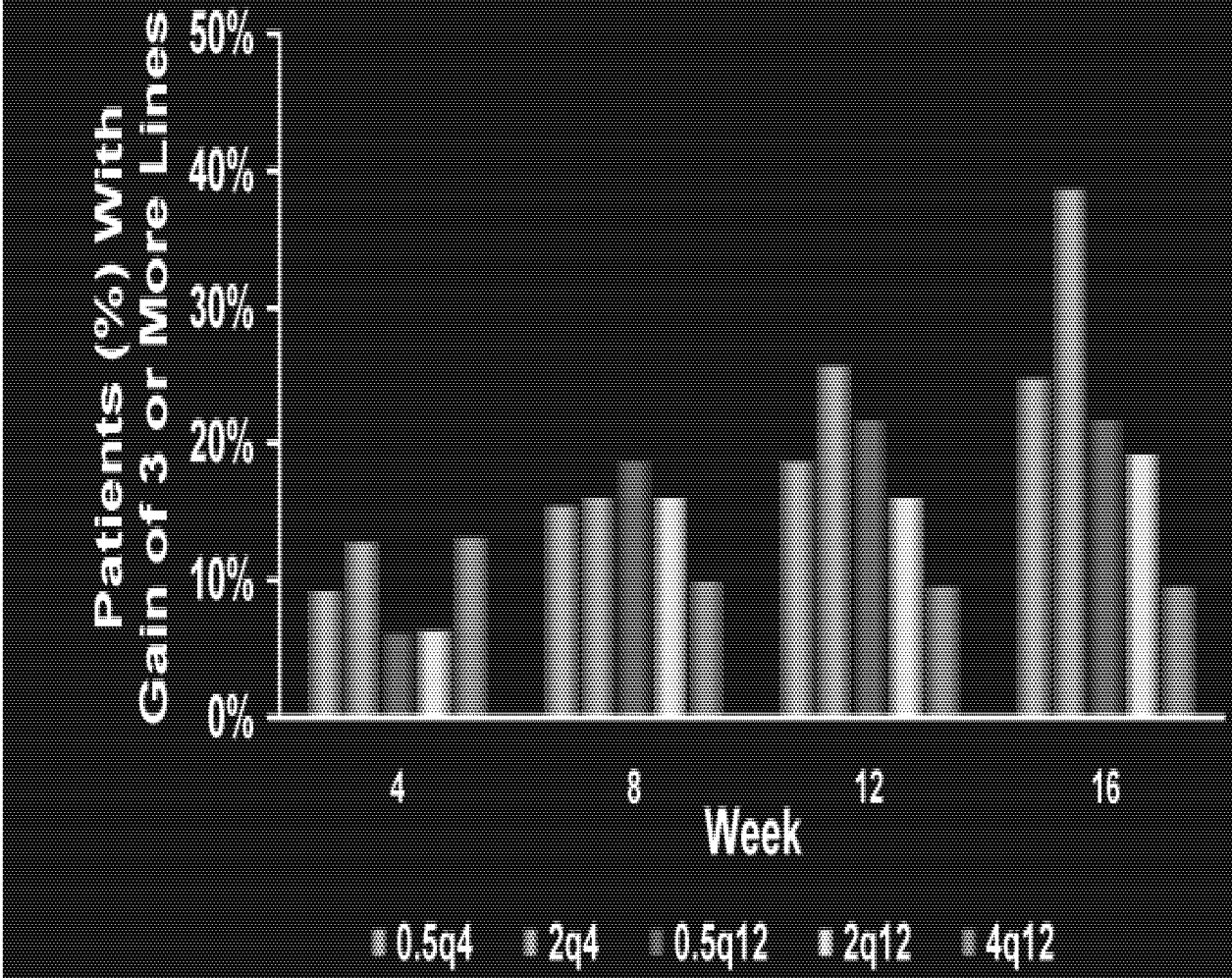
Improvement of ≥3 Lines of Visual Acuity: Improved With All Doses



LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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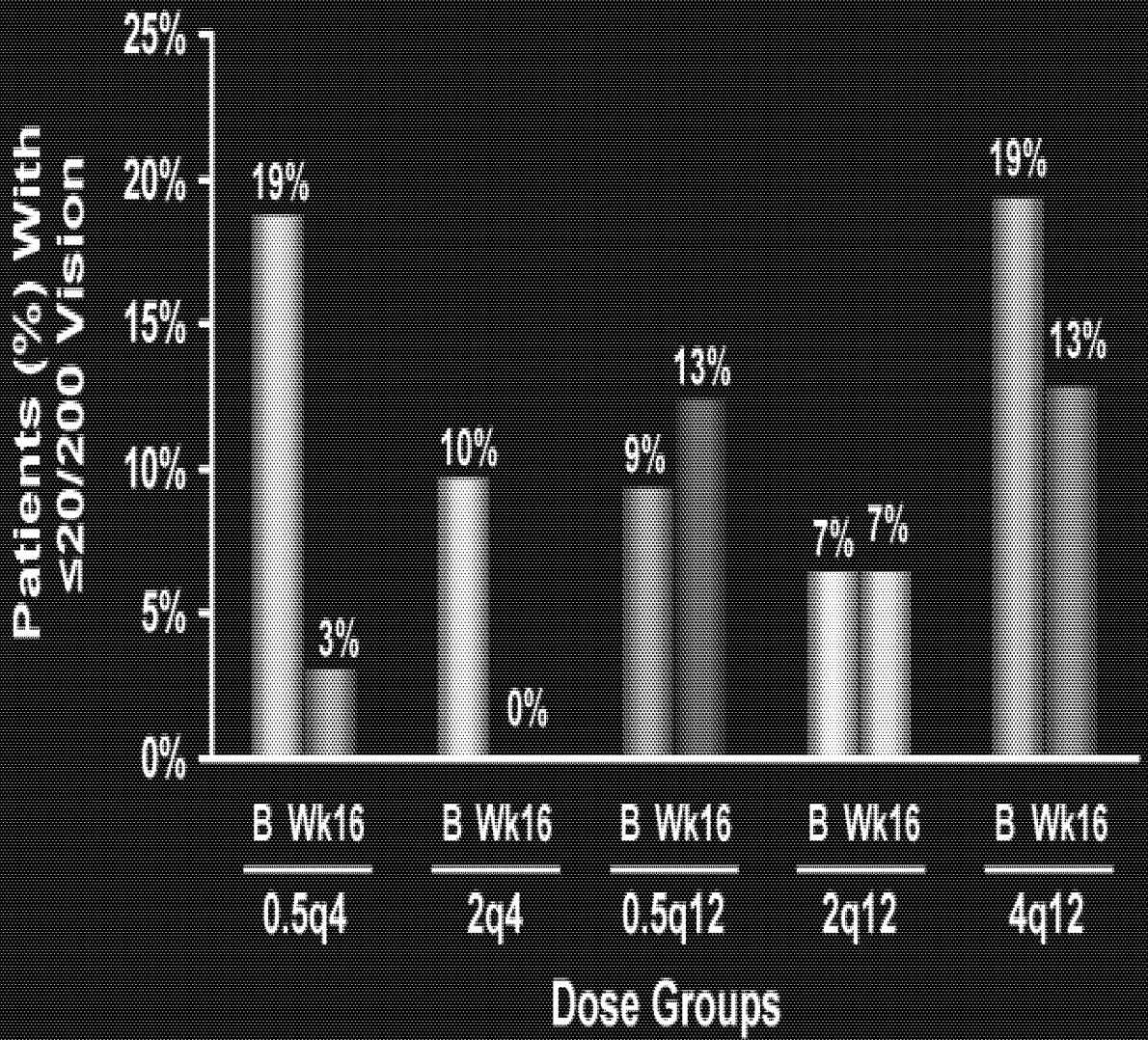
Proportion of Patients With ≤20/200 Vision Decreased With Monthly Dosing



B=baseline. LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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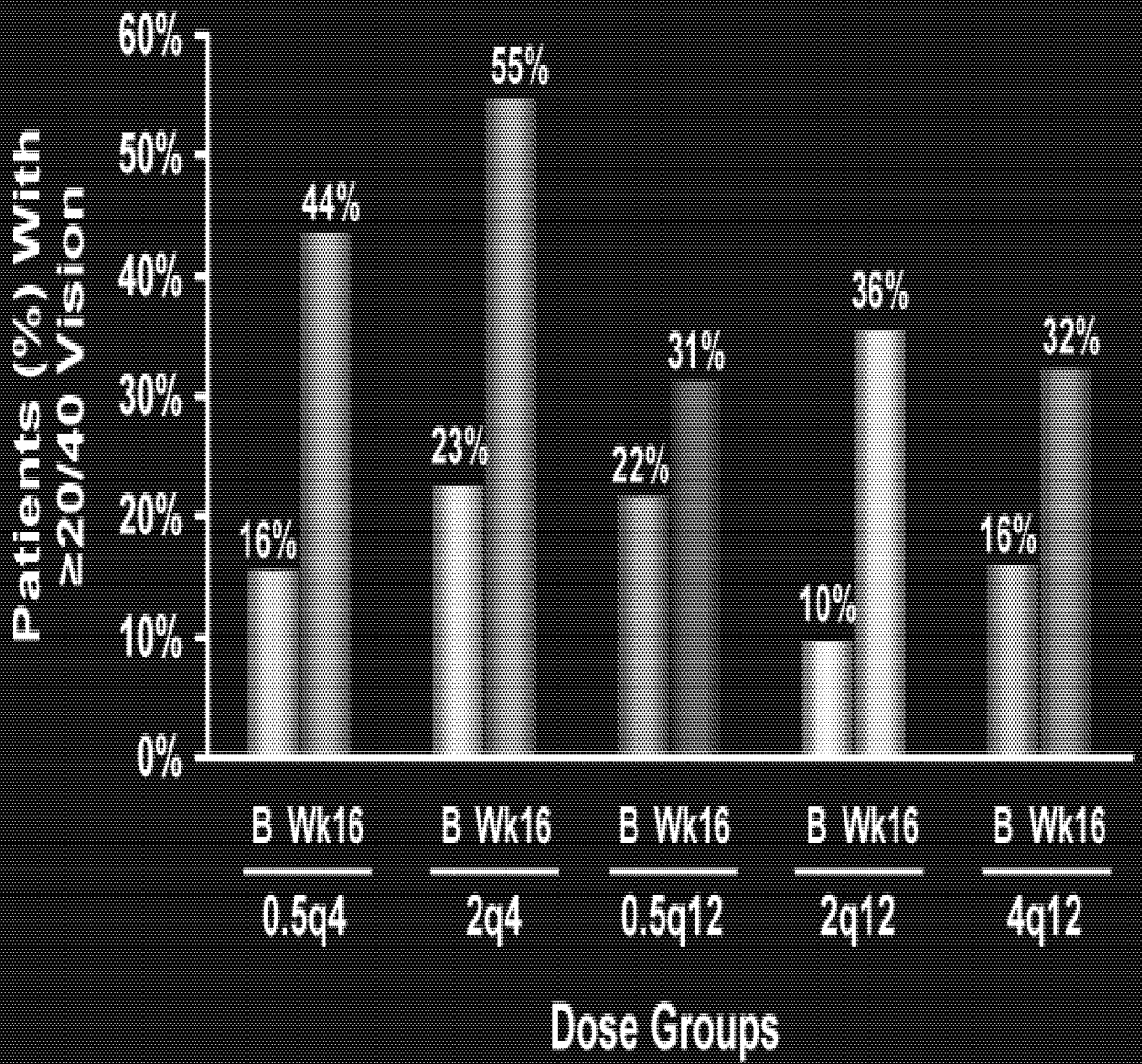
Proportion of Patients With ≥20/40 Vision Increased in All Dosing Arms



B=baseline. LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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Safety: Generally Well-Tolerated

- No ocular Serious Adverse Events (SAE) reported in study eyes
- No reports of clinically significant intraocular inflammation
- No incidence of endophthalmitis
- No drug-related systemic SAEs
- Non drug-related systemic SAEs:
  - 1 incident of angina pectoris (2q4 group)
  - 1 incident of congestive heart failure (0.5q4 group)
  - 1 incident of coronary artery disease (2q4 group)

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Safety: Treatment-Emergent Ocular Adverse Events Reported in > 5 Patients

Study Eye, All Groups Combined

Adverse Event	Number (N=157)	Percent (%)
Conjunctival Hemorrhage	38	24.2
Increased IOP (transient post injection)	21	13.4
Retinal Hemorrhage	13	8.3
Eye Pain	11	7.0
Vitreous Detachment	11	7.0
Detachment of Retinal Pigment Epithelium	9	5.7
Visual Disturbance	9	5.7
Visual Acuity Reduced (patient reported)	7	4.5
Retinal Pigment Epitheliopathy	6	3.8
Retinal Oedema	6	3.8

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Conclusions

- VEGF Trap-Eye significantly reduced retinal thickness from baseline, the primary study endpoint ($p<0.0001$)
- VEGF Trap also significantly improved visual acuity from baseline ($p<0.0001$)
- VEGF Trap-Eye 0.5 mg and 2 mg dosed every 4 weeks demonstrated the most improvement in retinal thickness and visual acuity at the 12-week primary endpoint and continued to show improvement at 16 weeks
  - 160-183 micron decrease in retinal thickness
  - 9.3-10.0 letter improvement in visual acuity
  - Reduction in number of patients with $\leq$20/200 vision to 0-3%
  - Increase in number of patients with $\geq$20/40 vision to 44-55%
- While quarterly dosing significantly improved retinal thickness and visual acuity versus baseline at all times, the effect was not as robust as with monthly dosing
  - A single dose maintained its effect on visual acuity out to 8 weeks
- Safety profile was predictable with no drug-related systemic side effects and no significant ocular inflammation

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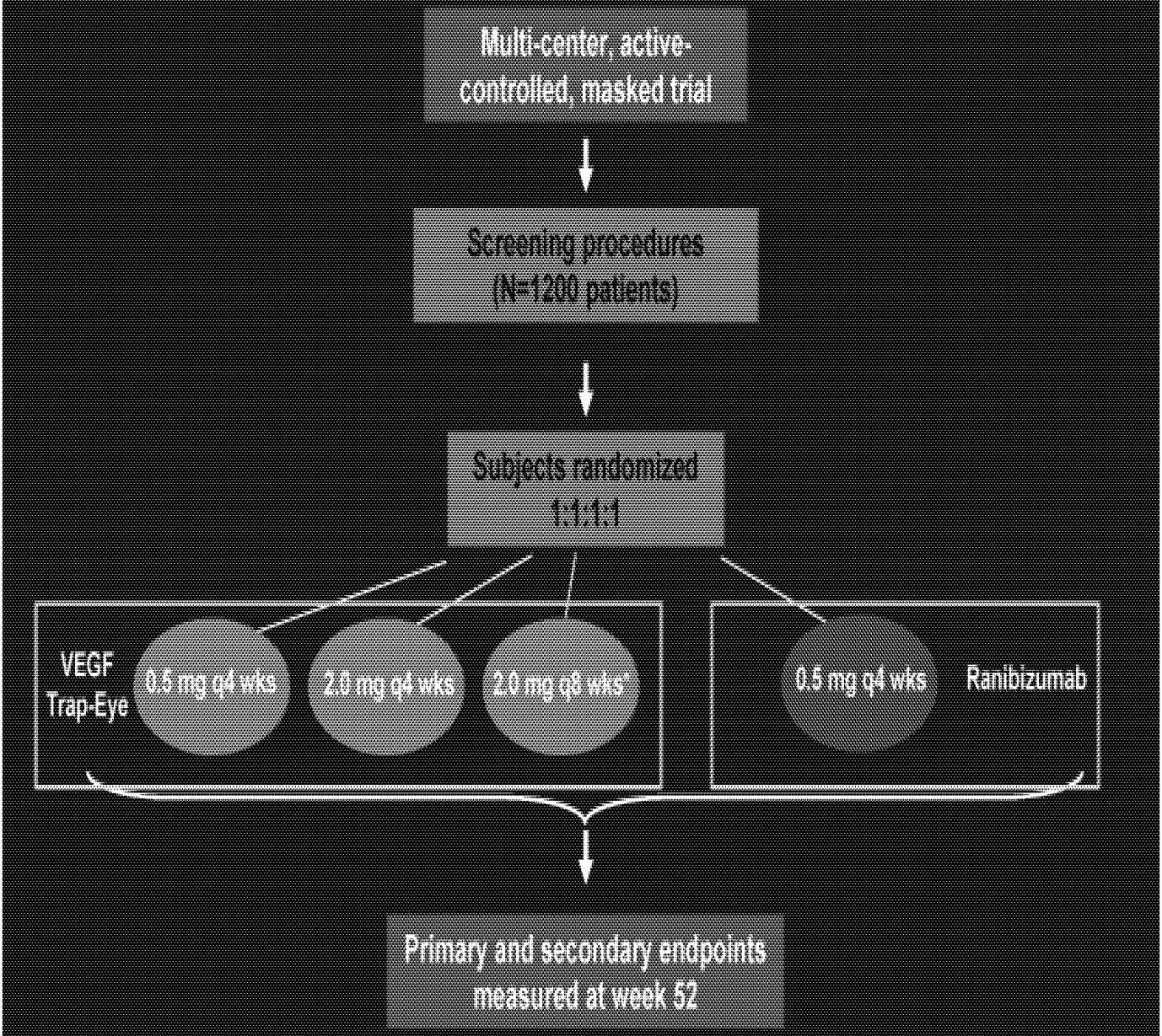
VIEW 1 Phase 3 Study Design
Currently Enrolling Patients



*After a 3-month monthly loading dose period.

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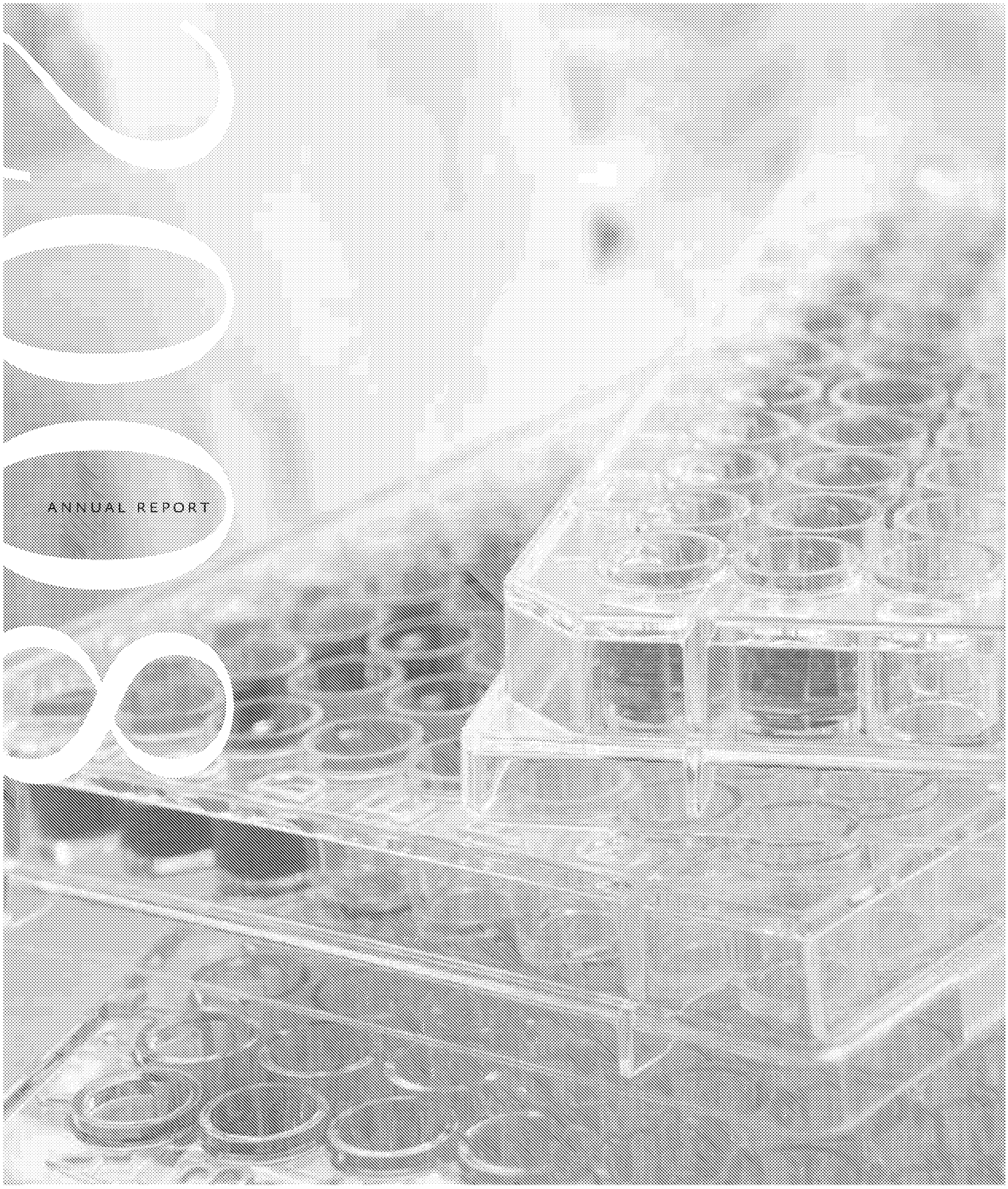

REGENERON

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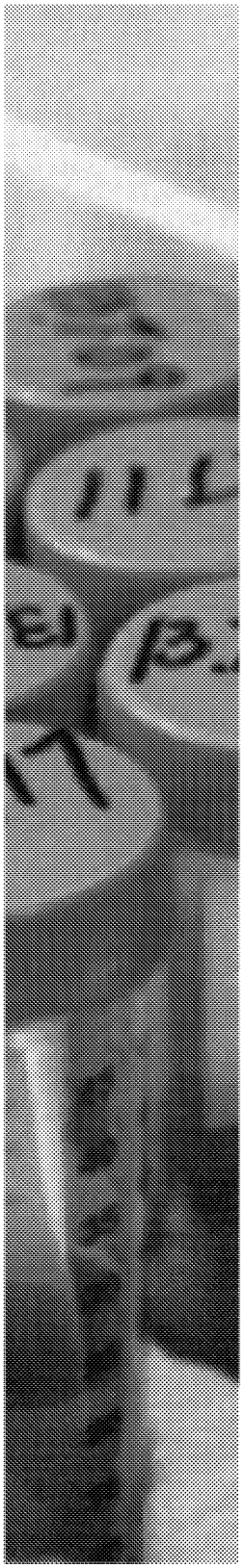

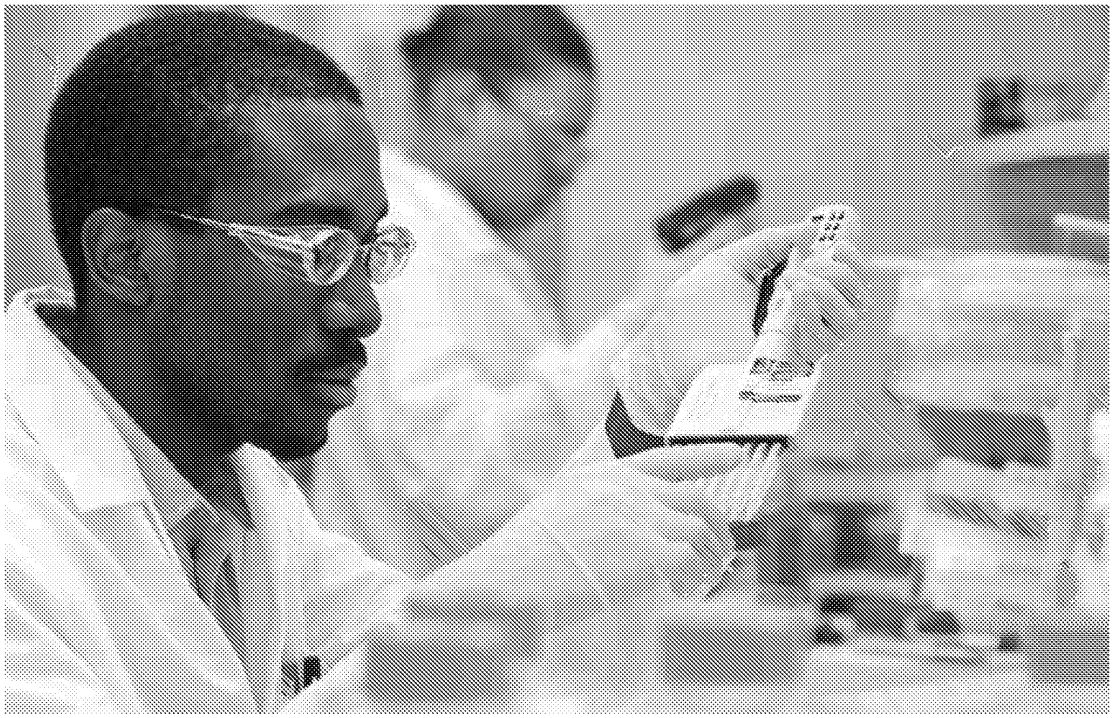

The Numbers…and Beyond

During 2008, Regeneron continued to execute on our long-term vision: to discover, develop, and commercialize medicines for the treatment of serious medical conditions. Much of our progress can be charted in numbers: sales of our first marketed product; clinical trials initiated and underway; new molecules discovered and advanced into development; and new employees brought on board to help our company move forward. But some things can't be quantified: the passion of our people for the work they do; the impact of ARCALYST® (rilonacept) Injection for Subcutaneous Use, our first marketed product, on the well-being of patients with Cryopyrin-Associated Periodic Syndromes or CAPS; and the potential of our pipeline to improve health for patients suffering from serious diseases.

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From 1 marketed product to 13 programs to $527 million in cash at year-end 2008, Regeneron's progress can be measured in numbers large and small.

LEONARD S. SCHLEIFER, M.D., PH.D.
President and Chief Executive Officer

P. ROY VAGELOS, M.D.
Chairman of the Board

GEORGE D. YANCOPOULOS, M.D., PH.D.
Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories

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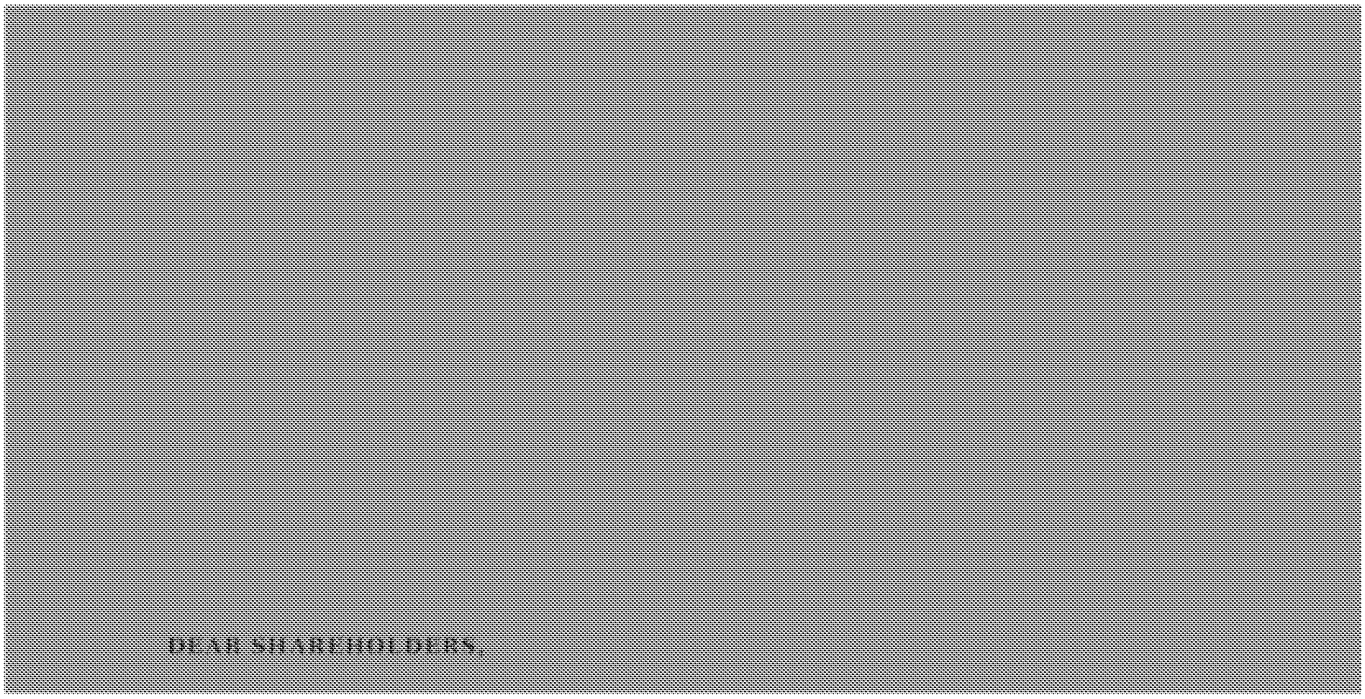

DEAR SHAREHOLDERS,

Reflecting on the past year, one observation stands out: Regeneron is a company that is advancing on all fronts. From discovery through development to manufacturing and commercialization, we have demonstrated our ability to execute our business plan for becoming a fully integrated biopharmaceutical company.

Over the last year:

- We launched our first marketed product, ARCALYST® (rilonacept), an inhibitor of the interleukin-1 cytokine, for Cryopyrin-Associated Periodic Syndromes (CAPS).
- We achieved positive Phase 2 results for rilonacept in drug-induced gout.
- We and sanofi-aventis advanced four Phase 3 studies with aflibercept, our drug candidate targeting Vascular Endothelial Growth Factor (VEGF), in various oncology settings—first-line metastatic hormone-refractory prostate cancer, first-line metastatic pancreatic cancer, second-line non-small cell lung cancer, and second-line metastatic colorectal cancer.
- We and sanofi-aventis started a Phase 2 study of aflibercept in first-line metastatic colorectal cancer.
- We and Bayer HealthCare continued to enroll patients in two Phase 3 studies with VEGF Trap-Eye in wet Age-related Macular Degeneration.
- We and Bayer HealthCare initiated a Phase 2 study of VEGF Trap-Eye in Diabetic Macular Edema.
- We and sanofi-aventis have three *VelocImmune*® antibody product candidates in clinical development and have advanced additional antibodies into preclinical development.
- We greatly expanded our R&D, clinical, and manufacturing capacities.
- We retired our debt and ended 2008 with $527 million in cash and securities.

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1 Approved Product

With FDA approval of ARCALYST® (rilonacept) as the first and only approved product for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), patients with these rare, hereditary, inflammatory conditions can now live their daily lives with fewer debilitating symptoms.

With the launch of ARCALYST, Regeneron now has the commercial infrastructure and capabilities in place that can be expanded to commercialize larger product opportunities in the United States.

$11 million in ARCALYST shipments in 2008

FROM DISCOVERY THROUGH COMMERCIALIZATION.

In February 2008, the U.S. Food and Drug Administration (FDA) granted marketing approval for ARCALYST 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. This was a watershed event for two important reasons. First, it brings needed relief to CAPS patients who have had no other approved treatment for their debilitating medical condition. During 2008, we transitioned patients who participated in the CAPS pivotal studies from clinical study drug to commercial supplies and shipped approximately **$11 million** of product. Second, FDA clearance demonstrates Regeneron's ability to discover a molecule and take it through clinical development and manufacturing, regulatory review, and commercialization. With the approval of ARCALYST, we can move forward with greater confidence in our ability not only to discover and develop new medicines, but also to manage the process through commercialization.

In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of rilonacept in preventing gout flares induced by the initiation of urate-lowering drug therapy, which is commonly used to control gout. In this 83-patient, double-blind, placebo-controlled study, over the first 12 weeks of urate-lowering therapy, the mean number of gout flares per patient in the rilonacept treatment

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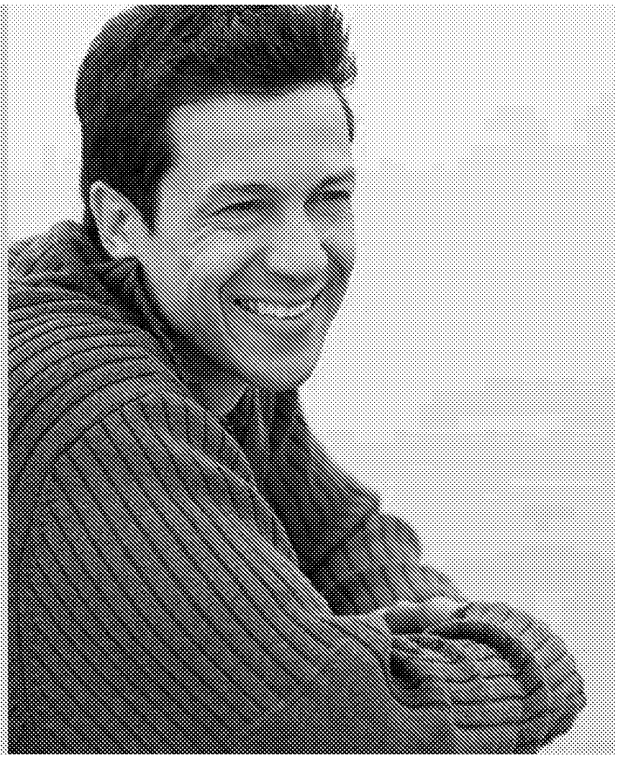

6 Investigational drugs in clinical development

We have drug candidates in all stages of clinical development that target a diverse set of serious conditions, including cancer, eye diseases, inflammatory diseases, and pain.

group was 81 percent lower than in the placebo group. Only 14.6 percent of patients treated with rilonacept experienced a gout flare compared to 45.2 percent of patients treated with placebo. No drug-related serious adverse events were reported in patients receiving rilonacept; injection-site reaction was the most commonly reported adverse event.

We are now enrolling patients in our Phase 3 rilonacept gout program which will include two studies in the prevention of gout flares in patients initiating urate-lowering therapy, one Phase 3 study evaluating rilonacept in the treatment of acute gout flares, and a separate safety study. Regeneron retains worldwide marketing rights to rilonacept.

In gout, uric acid crystals stimulate the production of interleukin-1, which causes an inflammatory response in the joints and surrounding tissues. An estimated one percent of the U.S. population suffers from gout, one of the most painful rheumatic diseases, and 1.4 million people are treated for acute gout attacks each year.

Beyond ARCALYST® (rilonacept), our development pipeline continues to expand and progress. Today we have **6** investigational drugs in clinical development, including three in Phase 3 trials.

VEGF TRAP-EYE.
Our VEGF Trap-Eye program showed strong progress during 2008. In September 2008, we and Bayer HealthCare announced the final one-year data from a Phase 2 study evaluating

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Regeneron currently has Phase 3 clinical trials underway targeting eye disease, various cancers, and gout. In Phase 3 clinical trials, new treatments are compared to either currently available therapies or placebo to assess effectiveness and safety.

Phase 3 Trials Underway

VEGF Trap-Eye in patients with the neovascular form of Age-related Macular Degeneration (wet AMD). Patients receiving VEGF Trap-Eye experienced improvements in vision and retinal thickness (an anatomic measure of treatment effect) during the 12 weeks of fixed monthly or quarterly dosing. These improvements were generally maintained over the next 40 weeks during which patients received VEGF Trap-Eye on a PRN (as needed) dosing schedule. During the PRN dosing period, patients received, on average, only two additional injections. There were no reported drug-related serious adverse events. The most common adverse events were those typically associated with intravitreal injections.

Currently, we and Bayer HealthCare are enrolling two Phase 3 studies of VEGF Trap-Eye in patients with wet AMD. These trials, involving 1200 patients each, are comparing treatment with VEGF Trap-Eye and Genentech's Lucentis® (ranibizumab), an anti-angiogenic agent approved for use in wet AMD. In 2008, we also initiated a Phase 2 study of VEGF Trap-Eye in patients with Diabetic Macular Edema (DME). Initial data from these studies are expected in 2010. Under our collaboration agreement, Bayer HealthCare has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales. We maintain exclusive rights to VEGF Trap-Eye in the United States.

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3 New antibodies in the clinic from the *VelociSuite*™ of technologies

Regeneron's *VelociSuite* of technologies is further accelerating the development of new product candidates. *VelociGene*® and *VelociMouse*® are designed to aid in the identification of specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. *VelocImmune*® increases the speed and efficiency of fully human monoclonal antibody development and is being used to generate antibodies to address clinically relevant targets of therapeutic interest.

AFLIBERCEPT IN ONCOLOGY.
In collaboration with sanofi-aventis, we have underway four Phase 3 studies of aflibercept (VEGF Trap) in combination with chemotherapy that are targeted to enroll a total of approximately 4000 patients. These studies are being conducted in first-line metastatic pancreatic cancer, first-line metastatic hormone-refractory prostate cancer, second-line non-small cell lung cancer, and second-line metastatic colorectal cancer. All studies are approximately 50 percent enrolled, and we expect initial data from three of the studies in 2010. In addition, a Phase 2 combination study of aflibercept in first-line metastatic colorectal cancer began in the first quarter of 2009.

We are also completing a Phase 2 study of single-agent aflibercept in patients with symptomatic malignant ascites, a condition where fluid accumulates in the abdominal cavity in women with advanced ovarian cancer. We expect initial data later this year.

With a total of **9** Phase 3 clinical trials underway or planned, Regeneron has made great strides in advancing the development of our clinical candidates. The progress we've recorded in our gout, eye, and cancer programs, along with the launch of our first marketed product, add up to a very positive year for our company. But they tell only a part of the Regeneron story. Building on our rich tradition of pioneering research, we have developed a suite of technologies for discovering, developing, and manufacturing fully human monoclonal antibodies. We are using this *VelociSuite* of technologies to generate our future pipeline of drug candidates. In fact, it would not be an overstatement to say that we are building a robust antibody development company within Regeneron, with **3** antibodies already in clinical development.

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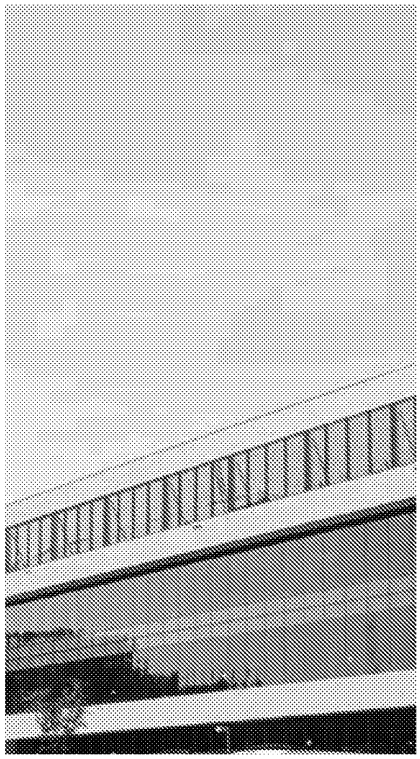
$527 million
in cash and securities at year-end 2008

Regeneron's cash reserves provide significant operating flexibility as we continue to advance our drug candidates through the development pipeline.

Including the funding from our collaboration agreements, our research and development programs are budgeted for over $500 million in spending in 2009. This leveraged spending has enabled us to build a world-class R&D capability.

Over $500 million
in 2009 budgeted R&D spending



MONOCLONAL ANTIBODY PROGRAM.
Our *VelociSuite*™ of technologies, including *VelocImmune*®, represents a unique platform for identifying and validating novel drug targets and for generating and manufacturing fully human monoclonal antibodies against these targets. In late 2007, we announced a major collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. The sanofi-aventis collaboration provides us with up to $100 million in research funding annually through 2012.

Three human antibodies developed under the sanofi-aventis collaboration are in clinical development: REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis; REGN421, an antibody to delta-like ligand-4 (Dll4) that is in development to disrupt angiogenesis in patients with cancer; and REGN475, an antibody against nerve growth factor (NGF) that is in development for the treatment of pain. We are on track with our goal to advance an average of two to three new antibodies into clinical development each year.

In September 2008, we also launched our Academic *VelocImmune* Investigators Program (Academic VIP) when we entered into an agreement to provide researchers at Columbia University Medical Center with access to the *VelocImmune* technology platform. In March 2009, we entered into a similar Academic VIP agreement with The University of Texas Southwestern Medical Center at Dallas. Under the agreements, scientists at the universities

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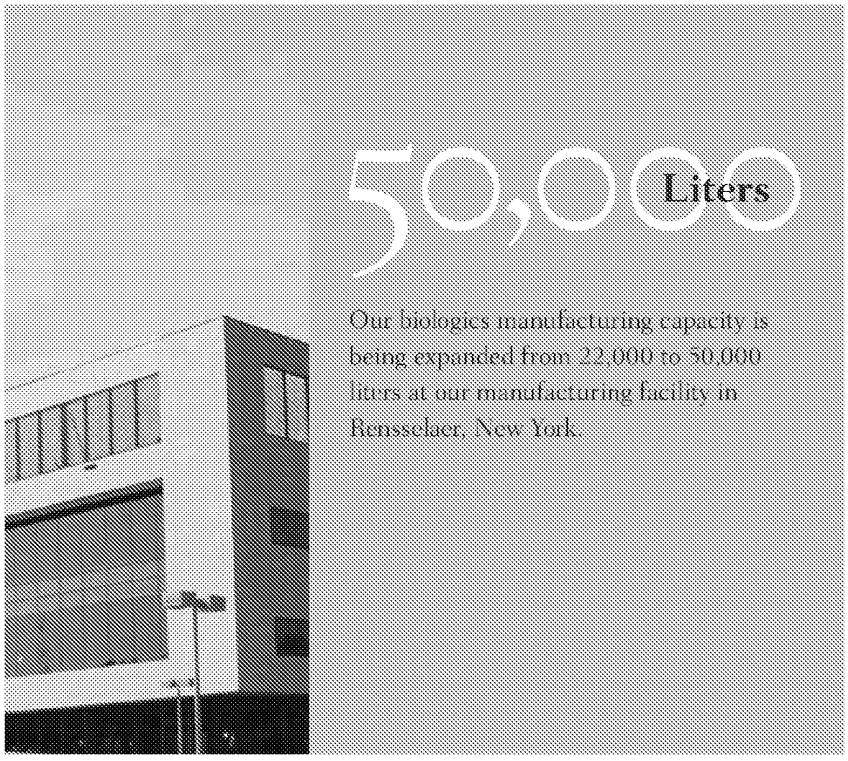

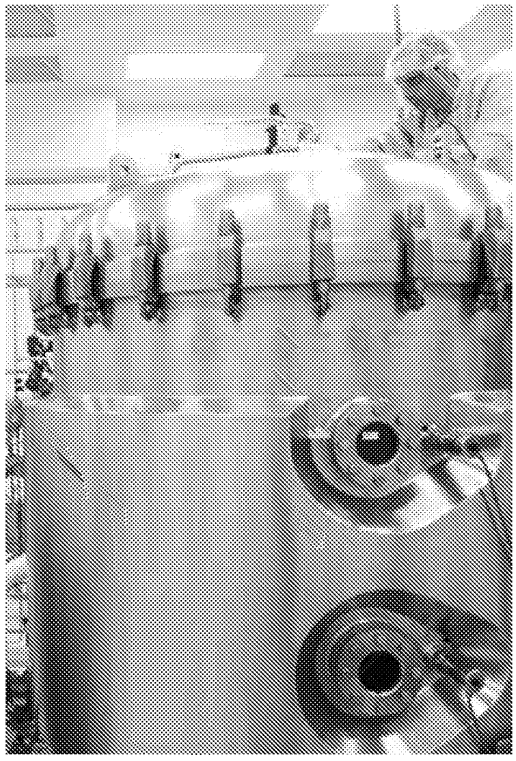

will use *VelocImmune*® mice to generate antibodies against their research targets and will conduct research to discover potential human therapeutics based on the antibodies. Regeneron has an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products. We see opportunities to enter into similar arrangements with other academic institutions.

FINANCIAL STRENGTH.

Clearly, there is a great deal of positive momentum at Regeneron, and we expect 2009 to be no less productive. Fortunately, we have the resources necessary to continue to move forward at this pace. Financially, we are well positioned. We finished 2008 with **$527 million** of cash and securities and no debt. What's more, our ongoing R&D spending will be largely funded by our collaborators. These collaborations are a strong vote of confidence in the promise of our discovery and development capabilities. They also provide significant investment leverage, enabling us to support an R&D program that we expect will exceed **$500 million** in 2009, including spending by sanofi-aventis and Bayer HealthCare.

We are expanding and enhancing our physical footprint to accommodate this level of activity. Later this year, we expect to move into two new buildings totaling 230,000 square feet at our existing Tarrytown, New York site. We are more than doubling our biologics manufacturing capacity to **50,000 liters** at our Rensselaer, New York facility. These are important investments in the future of our company.

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1000 Employees

We increased staff by 35 percent in 2008, primarily to expand our antibody discovery and development capabilities and to advance our clinical-stage product candidates. Now nearly 1000 strong, the highly-motivated Regeneron team is committed to the company's mission.

OUR PEOPLE.

But our most vital investment will always be in our people. During 2008, we launched a major recruiting effort designed primarily to support the antibody collaboration with sanofi-aventis. Our growing reputation in the medical and research communities has enabled us to attract top talent. By year-end 2009, we expect to grow to more than **1000 employees,** up from 682 at the end of 2007, and 919 at year-end 2008.

We will look to this talented group of professionals to continue the momentum we've achieved in the recent past. Last year's accomplishments moved us closer to our goal of having the pipeline, the discovery platform, the financing, and the people needed to bring breakthrough treatments to patients—and to building a world-class biopharmaceutical company for our shareholders.

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During 2013 we asked our employees what it is like to work at Regeneron. From their responses, we distilled and are now featuring in our employee recruiting program these five core attributes of our culture.

The Regeneron

Science drives our business and passion drives our science.

We believe great science leads to new and innovative drugs, which can improve people's lives, grow our company, and fund more great science.

We are a select team.

Regeneron has very high standards for hiring people. If you are talented enough to work here, then you join a team of dedicated people from all walks of life who work together to achieve our goals. Individual effort is rewarded, but true success only comes when we work together as a team.

You will be challenged. Every day.

No matter your role here, you will be expected to strive for excellence in your field. You will never stop learning and you will continually be sharing your knowledge with others.

"That's the way we've always done it" is the wrong answer.

We will not settle for the way things have always been done. At Regeneron, we are willing to see the world in our own way, and we're always looking for new and better ways to do things.

We won't let bureaucracy block good ideas.

Successful companies require organization and processes to function effectively. We have them too, but we work hard to ensure that unnecessary bureaucracy does not stand in the way of conducting great science and developing successful drugs.

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13 *Clinical Programs*

Potential

With drug candidates in all stages of clinical development, Regeneron has the expertise, infrastructure, resources, and corporate collaborations needed to move these candidates through the development process.

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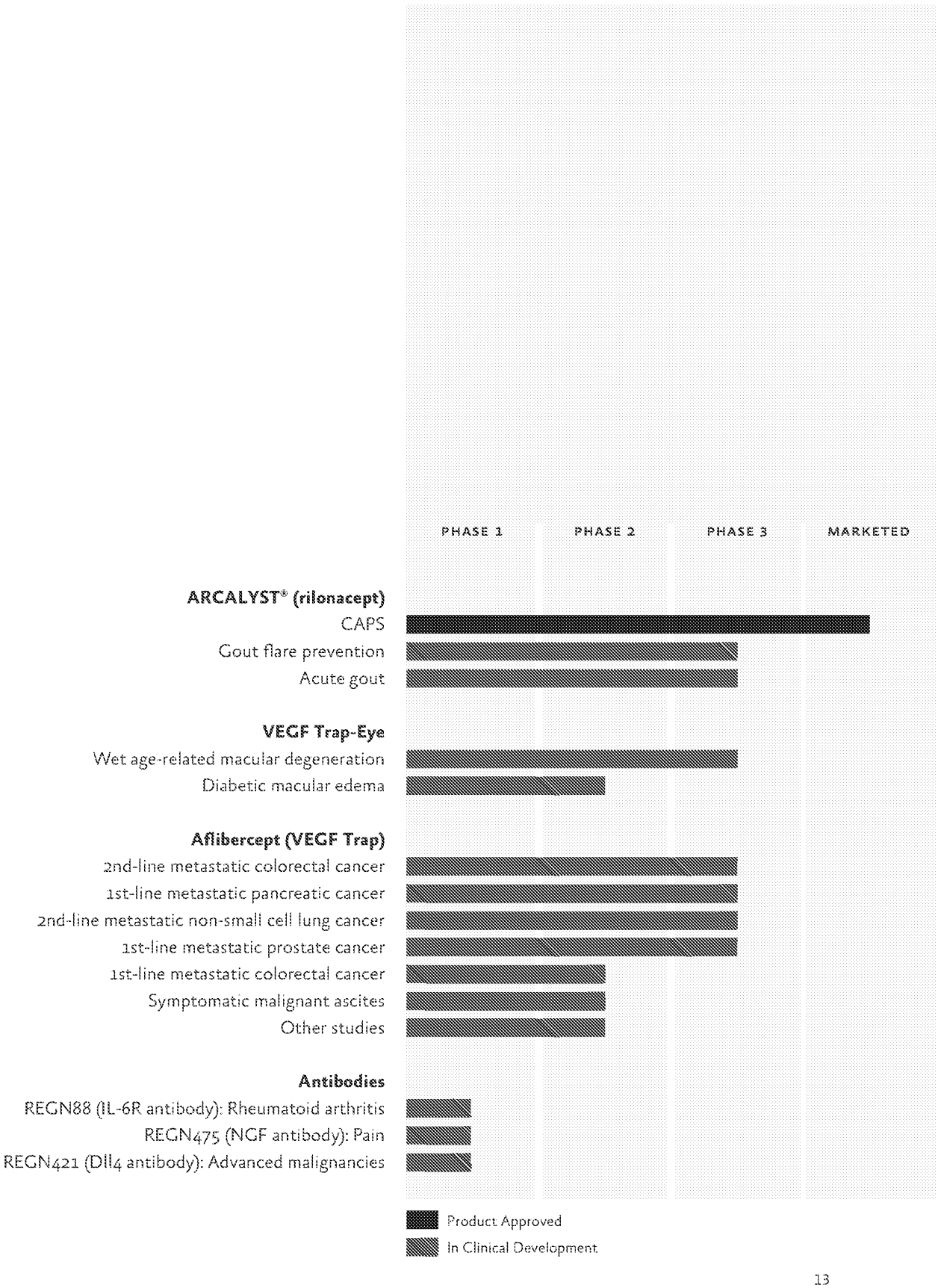

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CORPORATE INFORMATION

COMMON STOCK AND RELATED MATTERS

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.

2007	HIGH	LOW
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 April 14, 2009, there were 476 shareholders of record of our Common Stock and 42 shareholders of record of our Class A Stock. The closing bid price for the Common Stock on that date was $13.26.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

CORPORATE OFFICE

777 Old Saw Mill River Road
Tarrytown, NY 10591-6707
(914) 345-7400

SEC FORM 10-K

A copy of our annual report to the Securities and Exchange Commission on Form 10-K is available without charge from the Regeneron Investor Relations Department.

ANNUAL MEETING

The Annual Meeting will be held on Friday, June 12, 2009 at 10:30 a.m. at the Westchester Marriott Hotel, 670 White Plains Road, Tarrytown, NY 10591.

SHAREHOLDERS' INQUIRIES

Inquiries relating to stock transfer or lost certificates and notices of changes of address should be directed to our Transfer Agent, American Stock Transfer & Trust Co., 59 Maiden Lane, Plaza Level, New York, NY 10038, (800) 937-5449. General information regarding the Company, recent press releases, and SEC filings are available on our web site at www.regeneron.com, or can be obtained by contacting our Investor Relations Department at (914) 345-7741.

TRANSFER AGENT AND REGISTRAR

American Stock Transfer & Trust Co.
59 Maiden Lane
Plaza Level
New York, NY 10038

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PricewaterhouseCoopers LLP

REGENERON® and the following are registered trademarks of Regeneron Pharmaceuticals, Inc.: ARCALYST®, *VelocImmune*®, *VelociGene*®, and *VelociMouse*®. Lucentis® is a registered trademark of Genentech, Inc.

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CORPORATE DIRECTORY

DIRECTORS

P. Roy Vagelos, M.D.
Chairman of the Board
Retired Chairman of the Board
and Chief Executive Officer,
Merck & Co., Inc.

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Charles A. Baker
Retired Chairman of the Board,
President and Chief Executive Officer,
The Liposome Company, Inc.

Michael S. Brown, M.D.
Regental Professor and Director,
Jonsson Center for Molecular Genetics
The University of Texas
Southwestern Medical Center at Dallas

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Southwestern Medical School
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The University of Texas
Southwestern Medical Center at Dallas

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Regental Professor and Chairman,
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The University of Texas
Southwestern Medical Center at Dallas

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Retired Chairman of the Board
and Chief Executive Officer,
Prudential Financial, Inc.

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Professor Emeritus,
Department of Neurobiology,
Stanford University School of Medicine

George L. Sing
Chief Executive Officer, Stemmion, Inc.
Managing Director, Lancet Capital

George D. Yancopoulos, M.D., Ph.D.
Executive Vice President,
Chief Scientific Officer and President,
Regeneron Research Laboratories

SENIOR MANAGEMENT TEAM

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

George D. Yancopoulos, M.D., Ph.D.
Executive Vice President,
Chief Scientific Officer and President,
Regeneron Research Laboratories

Murray A. Goldberg
Senior Vice President,
Finance and Administration,
Chief Financial Officer, Treasurer
and Assistant Secretary

Stuart A. Kolinski
Senior Vice President,
General Counsel and Secretary

Peter Powchik, M.D.
Senior Vice President,
Clinical Development

Neil Stahl, Ph.D.
Senior Vice President,
Research and Developmental Sciences

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Senior Vice President,
Commercial

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Senior Vice President
and General Manager,
Industrial Operations and Product Supply

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Chapter 36
Clincal Development of VEGF Trap

John S. Rudge, Ella Ioffe, Jingtai Cao, Nick Papadopoulos, Gavin Thurston, Stanley J. Wiegand, and George D. Yancopoulos

Keywords: VEGF Trap, vascular eye disease, kinase inhibitors

Abstract: The inhibition of angiogenesis is proving to be an effective strategy in treating diseases involving pathological angiogenesis such as cancer and ocular vascular diseases. Since its discovery in the 1980s, vascular endothelial cell growth factor (VEGF) has been shown to play a vital role in both physiological and pathological angiogenesis, resulting in the development of numerous approaches to block VEGF and VEGF signaling, ranging from small molecule tyrosine kinase inhibitors to protein-based and RNA-based therapeutic candidates. VEGF Trap is one such protein-based agent that has been engineered to bind and sequester VEGF, as well as placental growth factor (PlGF), with high affinity. VEGF Trap has been shown to effectively inhibit pathological angiogenesis in numerous preclinical models of cancer and eye disease, and is now being evaluated in clinical trials in several types of cancer, as well as the 'wet' or neovascular form of age-related macular degeneration (AMD). This chapter will summarize the basic biology of VEGF and the progress of the VEGF Trap from the bench to the clinic.

Introduction

Angiogenesis is a vital process not only during development, but also in the adult in settings of wound repair and reproduction [1, 2]. However, in diseases characterized by uncontrolled, pathological angiogenesis, such as solid tumors or vascular diseases of the eye, inhibition of angiogenesis would be of therapeutic benefit. While diverse factors might be expected to regulate angiogenesis in different settings, a clear consensus is emerging that a single growth factor, VEGF is the critical requisite driver of both physiological and pathological angiogenesis in most settings [3]. Thus, while blocking VEGF signaling during early development can lead to severe growth retardation, it can also produce highly beneficial effects when applied to disease states characterized by pathological neovascularization [3]. Recent clinical studies have validated VEGF as a bona fide target for therapeutic intervention in cancer as well as in vascular diseases affecting the eye, such as wet AMD. These studies have led to approval by the U.S. Food and Drug Administration (FDA) of drugs that target the VEGF pathway, specifically antibodies directed against VEGF, or kinase inhibitors which block activation of the VEGF receptors [4–7]. Emerging therapeutic candidates that otherwise target VEGF signaling have also reported encouraging results [8].

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Biology of VEGF and Its Receptors

VEGF is widely known to promote angiogenesis, by stimulating vascular endothelial cell proliferation, migration and tube formation, and it can also markedly increase vascular permeability [9]. VEGF-A is the prototypical member of a family of factors that also consists of VEGF-B, VEGF-C, VEGF-D and PlGF, which bind differentially to VEGF receptors 1, 2 and 3 and neuropilin with different specificities [10,11]. In addition, alternative exon splicing results in the production of four major isoforms of human VEGF-A – $VEGF_{121}$, $VEGF_{165}$, $VEGF_{189}$, $VEGF_{206}$ differentiated by their heparin binding affinity [12]. $VEGF_{121}$ differs from the other isoforms in that it does not bind heparin and thus is freely diffusible. As the isoforms increase in molecular weight, they show increasing heparin binding affinity and consequently bind extracellular matrix such that they tend to be sequestered near their site of production [13–15]. Matrix metalloproteases (MMPs) appear to play an important role in regulating the release of these isoforms from matrix [16]. Although endothelial cells are the primary targets of VEGF actions, more recently it has been shown that other cell types, including monocytes, hematopoietic stem cells and neurons, can also respond to VEGF [17–19].

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The VEGF receptor 2 (VEGFR2) appears to be the major mediator of the mitogenic, angiogenic and pro-permeability actions of VEGF-A. Indeed, genetic deletion of VEGFR2 results in profound defects in embryonic vasculogenesis, including a failure to develop blood islands and organized blood vessels [20]. In contrast, the role of VEGFR1, which was the first VEGF receptor identified, is more difficult to discern [21]. To date, VEGFR1 has been implicated in MMP9 induction, hematopoiesis, and monocyte chemotaxis, and also appears to act as a 'biological sink' which sequesters VEGF from binding to the lower affinity receptor, VEGFR2 [11]. A further level of complexity was revealed when VEGF was shown to bind neuropilin, a molecule previously identified as a receptor for the collapsin/semaphorin family of ligands involved in axon guidance. The binding of VEGF to neuropilin is thought to result in presentation of VEGF to VEGFR2, augmenting VEGFR2 signal transduction [22].

The Evidence for VEGF as a Key Player in Tumor Angiogenesis

In situ hybridization studies have revealed that VEGF is highly expressed in a number of human tumors [23–27]. This is most apparent in renal cell carcinoma where mutations in the von Hippel-Lindau (VHL) tumor suppressor gene result in increased transcription of hypoxia-inducible factor (HIF1) genes [28,29].

Numerous preclinical studies have shown that the growth of many different tumor types can be inhibited using agents that variously inhibit VEGF signaling (small molecule inhibitors, VEGFR2 antibodies, soluble VEGF receptors including the VEGF Trap) [30–35]. These studies have also shown that VEGF derived from the stromal compartment, as well as the tumor itself, plays an important role in mediating the angiogenesis which supports tumor growth [32,36].

Not surprisingly, antiangiogenic therapy results in a cytostatic effect in many tumor types rather than frank regression. Thus, in many models, combination of VEGF blockade with chemotherapy or radiation therapy results in greater efficacy than either approach alone [37,38].

VEGF Pathway Inhibitors Approved for the Treatment of Cancer

Bevacizumab (Avastin®)

The positive results from preclinical studies have led to the testing of several VEGF inhibitors in clinical trials. These include the humanized anti-VEGF-A monoclonal antibody (bevacizumab, Avastin®), an anti-VEGFR antibody [39], small molecules that inhibit VEGFR signaling and VEGF Trap [4,40–42]. The first clinical validation of the anti-VEGF approach came with FDA approval of bevacizumab in 2004, based on the results of a randomized double-blind phase III trial in which bevacizumab was combined with bolus IFL (irinotecan, 5FU, leucovorin) chemotherapy as first line therapy for metatstatic colorectal cancer. Median survival increased from 15.6 months in the IFL alone arm to 20.3 months in the IFL + bevacizumab arm. Severe hypertension was observed in about 10% of bevacizumab treated patients, and gastrointestinal perforation was noted in ~2% of patients. In addition, the incidence of arterial thromboembolic complications (stroke, myocardial infarction, transient ischemic attacks, unstable angina) was double the incidence seen with chemotherapy alone [43].

Kinase Inhibitors

An alternative approach to using antibodies that bind and neutralize VEGF is the use of tyrosine kinase inhibitors that target the VEGF and other receptors. To date, two such kinase inhibitors have been approved by the FDA: SU11248 (sunitinib; Sutent®) and Bay 43–9006 (sorafenib; Nexavar®). Sunitinib inhibits tyrosine phosphorylation of VEGFR1, VEGFR2, platelet derived growth factor receptor (PDGFR), c-kit and Flt3, and has been approved for the treatment of Gleevec-resistant gastrointestinal stromal tumors (GIST) and metastatic renal cell carcinoma [7]. Sorafenib, which inhibits tyrosine phosphorylation of raf, VEGFR2/3, PDGFR, kit and Flt3, was approved in 2006 for the treatment of metastatic renal cell carcinoma [5,6]. It should be pointed out that these kinase inhibitors do not block VEGF signaling selectively or completely, and much of their clinical benefit could derive from the inhibition of other kinase pathways.

Development and Application of VEGF Trap in Preclinical Animal Models

Despite the important benefits in patient care provided by the currently approved VEGF pathway blockers, current evidence suggests that optimal VEGF blockade may not have yet been achieved (e.g., dose response studies do not indicate that saturation of benefit has been reached) [44,45], raising the possibility that more potent VEGF blockade could provide even more benefit for patients. The VEGF Trap may provide the opportunity to test this hypothesis, as it was designed to bind VEGF with exceedingly high-affinity. The VEGF Trap is a soluble chimeric receptor in which key domains of VEGFR1 (domain 2) and VEGFR2 (domain 3) are fused to the constant region (Fc portion) of human IgG1 [34]. This fully human protein is capable of binding all isoforms of VEGF-A with very high affinity (KD <0.5 pM for $hVEGF_{165}$). Moreover, and in contrast to antibodies directed against VEGF-A, the VEGF Trap also binds PlGF, a VEGF family member also implicated in pathological angiogenesis [46] (KD ~25 pM for hPlGF2). In addition, the VEGF Trap was engineered to exhibit excellent pharmacokinetic properties, and has a circulating half-life in humans of approximately 2–3 weeks, allowing for bi-weekly or even less frequent dosing.

Once VEGF Trap had been optimized, it was tested and shown to have significant antiangiogenic and anti-tumor efficacy in

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numerous preclinical tumor models [34,37,38,47–50]. When administered in combination with chemotherapy or radiation, VEGF Trap also produced a significant additive impact on tumor growth. Moreover, in an ovarian cancer model, VEGF Trap potently inhibited ascites formation [37,38,50]. The impressive efficacy profile of VEGF Trap in preclinical animal models justified its progression into clinical trials.

Interestingly, VEGF Trap also has an additional property that distinguishes it from antibodies: while antibodies form multimeric complexes with their antigens that are rapidly cleared from the systemic circulation, VEGF Trap forms an inert 1:1 complex with VEGF that remains in the circulation and can thus be readily measured. Thus, when given in doses that saturate VEGF binding, this unique property of the VEGF:VEGF Trap complex allows for the accurate determination of tumor and whole body VEGF production rates [51]. Somewhat surprisingly, when non-tumor bearing animals and humans are given the VEGF Trap, we find that total body production rates of VEGF are quite high, challenging previous claims that systemic VEGF levels can be used as a sensitive measure of tumor burden [51]. This finding has the important corollary that agents designed to bind and inactivate tumor-derived VEGF must be provided in amounts sufficient to ensure that they are not effectively consumed by the large amounts of VEGF normally produced by the body. Building on this finding, we have determined that measurement of the levels of free and bound VEGF Trap provides a clear index of the doses required to capture all available VEGF, offering a useful guide for dosing of this antiangiogenic agent. Based on these assays, the doses currently being used in the clinic for cancer appear to be in the therapeutic range.

VEGF Trap in Clinical Trials for Cancer

Multiple Phase 1 trials have been carried out using the VEGF Trap as a single agent, or in combination with various chemotherapeutic regimens, in patients with advanced cancers, with more than 300 patients treated to date. Numerous objective responses as well as cases of prolonged stable disease have been noted in these trials. Interestingly, in addition to anti-tumor responses, improvements in tumor-associated co-morbidities have been observed: in particular, substantial or complete resolution of tumor-associated ascites. The major adverse events noted in these trials are consistent with those seen with other anti-VEGF agents, and include hypertension and proteinuria. Importantly, no antibodies to VEGF Trap were observed in any patients.

VEGF Trap is currently in Phase II clinical trials and is about to initiate multiple large Phase 3 trials. Preliminary results from two of these studies were recently reported at the American Society of Clinical Oncology 2007 annual meeting [41,42] Results were reported from an interim analysis of a randomized, double-blind, multi-center Phase 2 trial comparing two doses of VEGF Trap in patients with recurrent, platinum-resistant epithelial ovarian cancer. The patients selected for this study were heavily pre-treated and had failed several other treatment regimens. While the study remains blinded with respect to dose, the pooled preliminary results from both the high and low dose groups demonstrated anti-tumor activity, as evidenced by an 8% objective tumor response rate, with a 13% response rate as measured by a 50% reduction in circulating levels of the tumor marker CA-125. Disease was judged to be stable in 77% of patients at 4 weeks, and in 41% of patients at 14 weeks. In addition, of 24 patients in the study who had tumor-associated ascites, 29% experienced complete resolution of their ascites while 54% experienced no increase in ascites during treatment. Tolerability was similar to other molecules in this class with hypertension being the most common grade 3/4 event (16%). Two patients (1.2%) experienced bowel perforation, both of whom recovered. In a collaboration involving Sanofi-Aventis and Regeneron Pharmaceuticals, the ongoing single-agent studies of VEGF Trap will be complemented by a large Phase 3 program combining VEGF Trap with standard chemotherapy regimens in at least 5 different advanced solid tumors: colorectal, non-small cell lung, prostate, pancreas and gastric cancer, with the first of these studies initiating in 2007.

Preclinical Studies with VEGF Trap in Vascular Eye Diseases

The finding that VEGF-A was up-regulated in the aqueous and vitreous humor of patients with proliferative diabetic retinopathy extended the focus of antiangiogenic agents from cancer to vascular eye disease [52,53]. Wet age-related macular degeneration (AMD) is the most common cause of vision loss in the elderly [53,54]. In this disease, VEGF is believed to mediate the abnormal growth of choroidal vessels that, together with the associated vascular leak and edema, disrupts the normal retinal architecture. VEGF Trap has also been tested in a number of rodent models of ocular vascular disease, where it has been shown to inhibit choroidal [55] and corneal [56] neovascularization in addition to suppressing vascular leak in the retina [57]. VEGF Trap has also been shown to improve the survival of corneal transplants [58]. In a primate model of AMD, in which a laser was used to induce choroidal vascular lesions, intravitreal administration of VEGF Trap was found not only to prevent the development of vascular leak and neovascularization when administered before the time of injury but also completely resolved vascular leak when administration was delayed until after the lesions had fully developed [59].

VEGF Trap in Clinical Trials for Vascular Eye Disease

The promising results in preclinical models supported the introduction of VEGF Trap into the clinic for treatment of both wet AMD and diabetic macular edema, using a version of VEGF Trap specifically formulated for intra-ocular administration,

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termed VEGF Trap-Eye. Following successful completion of Phase I studies in wet AMD, VEGF Trap-Eye has progressed to a Phase 2 trial, for which interim results were recently presented at the Association for Research in Vision and Ophthalmology (ARVO) 2007 annual meeting [60,61]. In this trial, VEGF Trap-Eye was given at monthly intervals at doses of 0.5 or 2.0 mg, or as a single injection of 0.5, 2.0 or 4.0 mg. In the interim analysis, VEGF Trap-Eye met the pre-specified primary endpoint of reducing retinal thickness as measured by ocular coherence tomography (OCT) at 12 weeks compared with baseline (all groups combined, decrease of 135 μm, $P < 0.0001$). Mean change in visual acuity, a key secondary endpoint of the study, also demonstrated a statistically significant improvement (all groups combined, increase of 5.9 letters, $P < 0.0001$). Interestingly, patients in the highest monthly dose group achieved an average vision gain of more than 10 letters at 12 weeks, and even a single injection of VEGF Trap-Eye resulted in improved mean visual acuity at 12 weeks (all dose levels combined). Thus, the increased potency of VEGF Trap-Eye may offer the potential for improved efficacy and/or longer dosing intervals compared to the current standard of care [62–64]. In the VEGF Trap-Eye Phase 2 trial, there were no drug-related serious adverse events, and treatment with the VEGF Trap-Eye was generally well-tolerated. The most common adverse events were those typically associated with intravitreal injections. A Phase III program for VEGF Trap-Eye in wet AMD will be initiated in 2007.

In addition, as reported at ARVO 2007 [60,65], a Phase 1 study of VEGF Trap-Eye in diabetic macular edema (DME) showed that a single intravitreal injection in patients with longstanding diabetes resulted in a marked decrease in mean central retinal thickness and mean macular volume throughout the 6 week observation period. Additional trials with VEGF Trap-Eye in DME are anticipated in the future.

Conclusion

The VEGF Trap is an all human, chimeric receptor-based protein engineered to potently bind all forms of VEGF-A and PlGF, and to exhibit superior pharmacokinetic properties. The promise of the VEGF Trap in preclinical models of cancer and vascular eye diseases is being maintained during its initial evaluation in Phase 1 and 2 human trials, offering the hope that this therapeutic candidate may offer additional benefit to patients suffering from cancer or blinding vascular eye diseases.

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ARVO Annual Meeting Abstract | April 2011

Primary Results of an International Phase III Study Using Intravitreal VEGF Trap-Eye Compared to Ranibizumab in Patients with Wet AMD (VIEW 2)

Ursula Schmidt-Erfurth; Victor Chong; Bernd Kirchhof; Jean-Francois Korobelnik; András Papp; Majid Anderesi; Georg Groetzbach; Bernd Sommerauer; Rupert Sandbrink; Yuichiro Ogura

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Investigative Ophthalmology & Visual Science April 2011, Vol.52, 1650. doi:

Abstract

Purpose: : To evaluate efficacy and safety of different dose and interval regimens of VEGF Trap-Eye (VTE) vs monthly ranibizumab in patients with choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD) at 12 months in a international setting.

Methods: : A total of 1240 patients from Europe, Latin America, Asia, and Australia were randomized to VTE 0.5 mg monthly (4 weeks; 0.5q4wk), 2 mg monthly (2q4wk), 2 mg every two months (8 weeks; 2q8wk) following 3 monthly doses, or ranibizumab 0.5 mg monthly (Rq4wk). The primary endpoint was the proportion of patients maintaining vision (loss <15 ETDRS letters) from baseline to week 52. Secondary endpoints included mean change in best corrected visual acuity (BCVA) at Week 52. Central retinal thickness was assessed monthly.

Results: : There were 72.4% Caucasian and 21.6% Asian patients included. The proportions of patients maintaining vision at week 52 were 94.4%, 96.3%, 95.6%, and 95.6% for Rq4wk, 0.5q4wk, 2q4wk, and 2q8wk, respectively. All VTE arms were non-inferior to ranibizumab. Mean improvements in BCVA for Rq4wk, 0.5q4wk, 2q4wk and 2q8wk were 9.4, 9.7, 7.6, and 8.9 letters; differences between the VTE arms and Rq4wk were non-significant. The incidences of ocular treatment emergent adverse events (AEs) were similar across all treatments, with the most frequent AEs associated with the injection procedure, the

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underlying disease, and/or the aging process. Conjunctival hemorrhage, macular degeneration, retinal hemorrhage, and reduced visual acuity were the most frequent ocular AEs. There were no concerns regarding systemic safety in any arm.

Conclusions: : Across different ethnicities, VEGF Trap-Eye monthly or every two months was non-inferior to monthly treatment with ranibizumab with a favorable safety profile. Based on the study data, the new management paradigm in wet AMD with treatment every two months using VEGF Trap-Eye can be recommended regardless of the ethnicity.

Clinical Trial: : http://www.clinicaltrials.gov NCT00637377

Keywords: age-related macular degeneration • vascular endothelial growth factor

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ARVO Annual Meeting Abstract | April 2010

Influence of Baseline Angiographic Classification on Outcomes in the CLEAR-IT 2 Phase 2 Study of Intravitreal VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration

J. S. Slakter; CLEAR-IT 2 Study Group

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science April 2010, Vol.51, 2055. doi:

Abstract

Purpose: : To determine if treatment outcomes for patients enrolled in the CLEAR-IT 2 study of VEGF Trap-Eye in patients with neovascular AMD were influenced by baseline fluorescein angiographic characteristics, including the presence of cystoid macular edema (CME), retinal angiomatous proliferation (RAP), and serous pigment epithelial detachments (PEDs).

Methods: : CLEAR-IT 2 was a randomized, multicenter, prospective dose and dose-interval ranging study designed to assess the safety and efficacy of VEGF Trap-Eye in patients with subfoveal choroidal neovascularization secondary to AMD. Patients with neovascular AMD (n=157) received VEGF Trap-Eye 0.5 or 2.0 mg monthly or 0.5, 2.0, or 4.0 mg quarterly for 12 weeks, followed by PRN dosing to 1 year. Anatomic efficacy measures were assessed using optical coherence tomography (OCT) and fluorescein angiography (FA). All OCT and FA images were assessed by central reading centers. A subanalyis was performed for patients who entered the study with CME (n=12), RAP lesions (n=7), and serous PED (n=10).

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Results: : For all groups combined (n=157), mean change in visual acuity from baseline at 1 year was 5.3 letters (p<0.0001) with 63 of the 157 patients (40%) gaining 2 or more lines. The mean change in central retinal/lesion thickness from baseline was -130µm (p< 0.0001) at 1 year. For patients with RAP lesions at baseline, mean change in visual acuity at week 52 was + 6.3 letters, with 4 of the 7 patients gaining 2 or more lines. For patients with CME at baseline, mean change in visual acuity at week 52 was +12 letters with 8 of the 12 patients gaining 2 or more lines. For patients with serous PED at baseline, mean change in visual acuity at week 52 was +6.7 letters, with 5 of the 10 patients gaining 3 or more lines.

Conclusions: : VEGF Trap-Eye produced significant improvements in visual acuity in patients with CME, RAP lesions, and serous PEDs similar to those seen with the overall patient population.

Clinical Trial: : www.clinicaltrials.gov NCT00320788

Keywords: age-related macular degeneration • choroid: neovascularization • vascular endothelial growth factor

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ARVO Annual Meeting Abstract | April 2009

A Phase 2, Randomized, Controlled Dose- and Interval-Ranging Study of Intravitreal VEGF Trap-Eye in Patients With Neovascular Age-Related Macular Degeneration: Optical Coherence Tomography (OCT) and Fluorescein Angiography (FA) Outcomes at 1 Year

J. S. Slakter; CLEAR-IT 2 Investigators

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science April 2009, Vol.50, 1890. doi:

Abstract

Purpose: : To present 1 year data on VEGF Trap-Eye, a fusion protein that penetrates all retinal layers binding with high affinity to all VEGF-A isoforms and placental growth factor, with special emphasis on anatomic outcomes as measured by optical coherence tomography (OCT) and fluorescein angiography (FA).

Methods: : In this randomized, double masked, multi-center Phase 2 trial, patients with neovascular AMD received VEGF Trap-Eye 0.5 or 2.0 mg monthly or 0.5, 2.0, or 4.0 mg quarterly for 12 weeks, followed by PRN dosing to 1 year. Anatomic efficacy measures included changes from baseline in central retinal/lesion thickness (CR/LT), total macular volume (TMV), and pigment epithelial defect thickness (PED) as measured by OCT, and total lesion area and choroidal neovascularization (CNV) area as determined by FA. All OCT and FA images were assessed by central reading centers.

Results: : One year results for all groups combined (n=157) demonstrated significant decreases from baseline in CR/LT of -130μm ($p< 0.0001$), in TMV of -1.1 mm^3 ($p< 0.0001$) and in PED thickness (n = 46 with PED at baseline) of -102μm. All groups combined at 1

year showed a modest decrease from baseline in total lesion size (mean change of -0.39 mm^2), and significant reductions of active CNV size (mean change of -2.21 mm^2, $p< 0.0001$) and classic CNV size (mean change of -1.21 mm^2, $p< 0.0001$). Patients dosed with 2 mg monthly for 12 weeks followed by PRN dosing, in general, achieved the largest improvements in anatomic as well as visual acuity measures.

Conclusions: : VEGF Trap-Eye produced significant reductions in CR/LT, TMV and PED thickness as well as significant reductions in CNV and classic CNV size at 1 year compared to baseline.

Clinical Trial: : www.clinicaltrials.gov NCT00320788

Keywords: age-related macular degeneration • choroid: neovascularization • vascular endothelial growth factor

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Electronic Acknowledgement Receipt	
EFS ID:	40026640
Application Number:	16397267
International Application Number:	
Confirmation Number:	8135
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Customer Number:	96387
Filer:	Karl Bozicevic/Kimberly Zuehlke
Filer Authorized By:	Karl Bozicevic
Attorney Docket Number:	REGN-008CIPCON5
Receipt Date:	16-JUL-2020
Filing Date:	29-APR-2019
Time Stamp:	18:49:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

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11	Non Patent Literature	67_Regeneron_2008_Annual_Report.pdf	1596074 8dbf34e475eefe9794c43995ca33ef81563cbc25	no	20
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Information:					

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Information:					
		Total Files Size (in bytes):	208276899		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

annual report 2009

science drives our business

REGENERON

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Clinical programs

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and passion drives our science

Regeneron is at one of the most exciting moments in its history. We've selected the messages and images in the opening section of this Annual Report to evoke who we are and what we do as we strive to bring innovative new medicines to patients in need.

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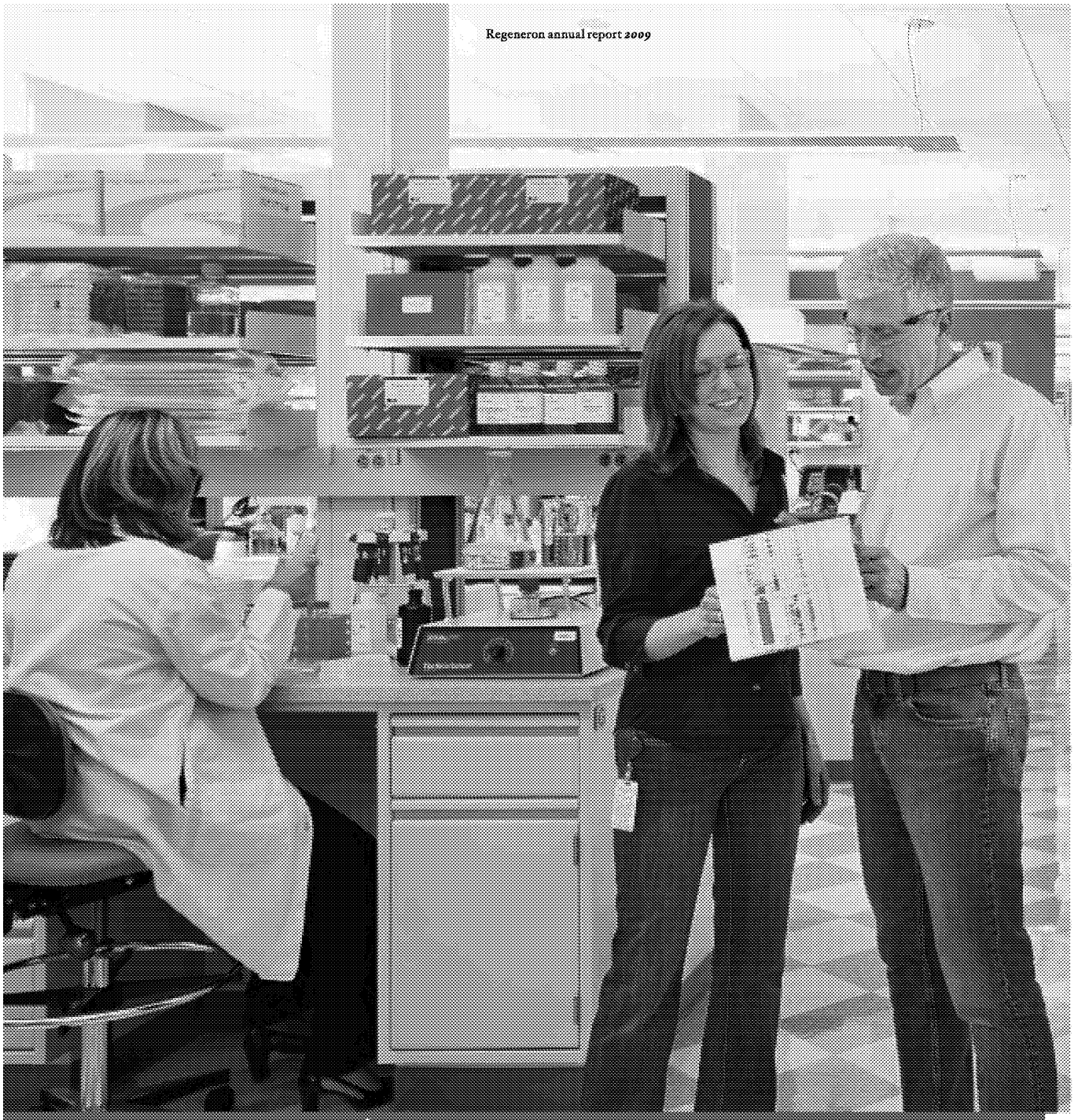

science drives our business

Innovative science was and remains the foundation of our company. Discovery is our lifeblood. All our drug candidates come from our own laboratories, based on proprietary technologies that we developed for creating fully human monoclonal antibodies and fusion proteins we call Traps.

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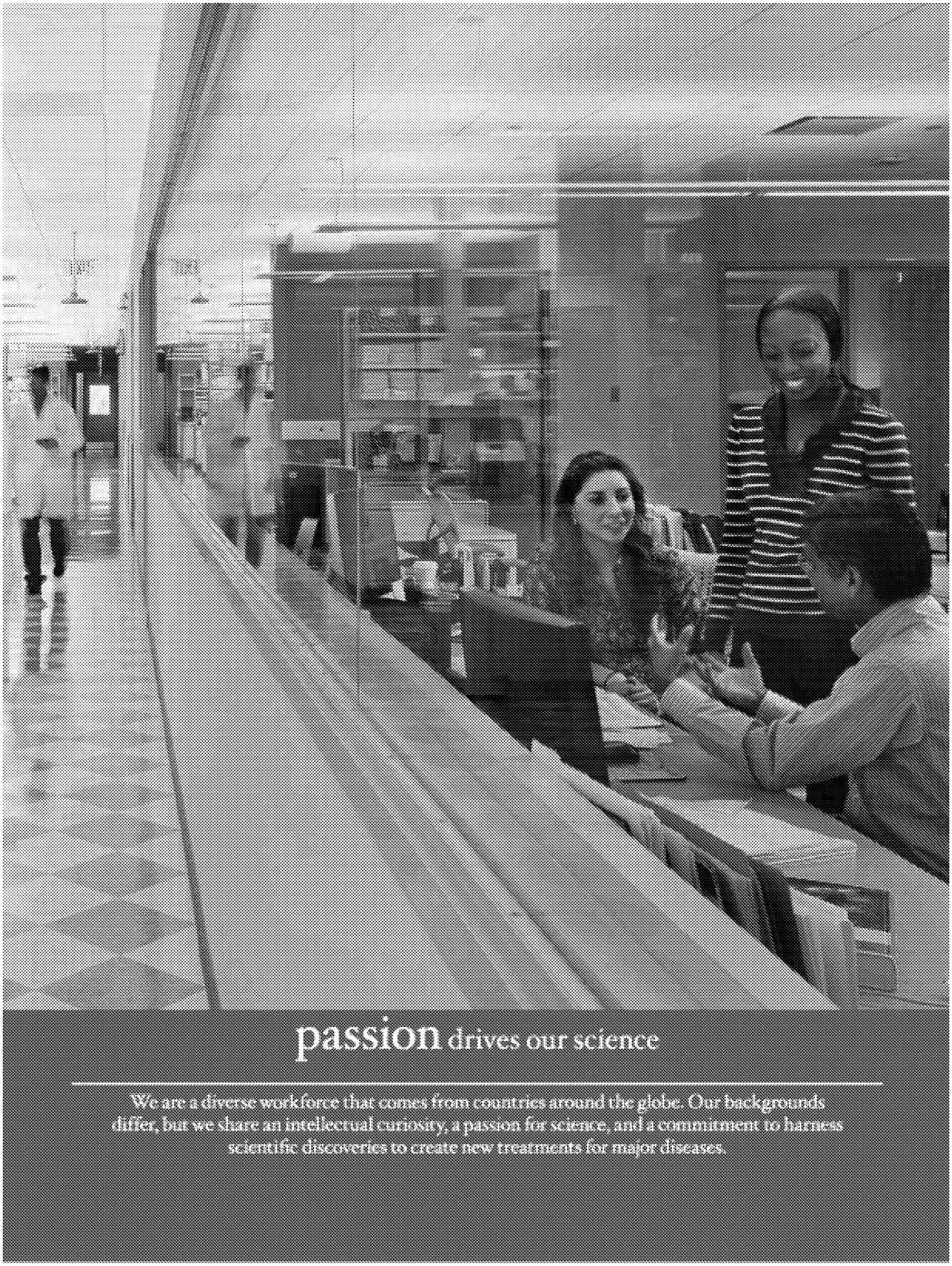
passion drives our science
We are a diverse workforce that comes from countries around the globe. Our backgrounds differ, but we share an intellectual curiosity, a passion for science, and a commitment to harness scientific discoveries to create new treatments for major diseases.

we are becoming big

We operate on a large scale. We have eight product candidates in clinical development for 19 different indications. Our research and development spending, including expenditures by our collaborators on partnered programs, topped $570 million in 2009 and should exceed $700 million in 2010. To support our growing pipeline, we employ over 1,000 people and expect to add about another 300 employees by year-end.

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we value small

We retain the nimble, entrepreneurial culture of a small company. We avoid unnecessary bureaucracy and strive to maintain the values and practices that have brought us to where we are today and that attract and motivate our talented workforce. These include challenging people every day; encouraging reasonable risk taking, which requires giving people the freedom to fail; appreciating individual initiative as part of group efforts; and moving rapidly from ideas to implementation.

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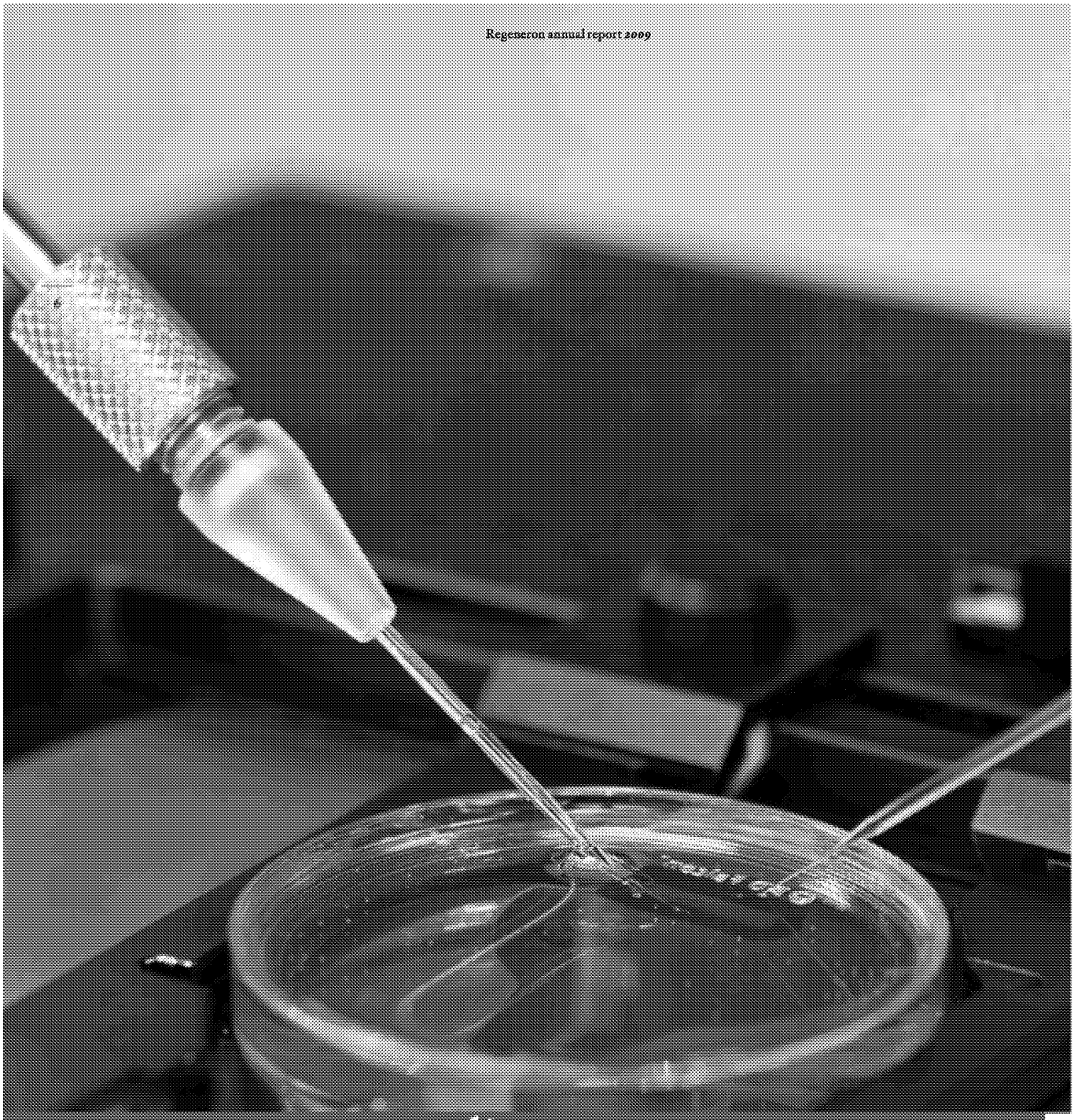

we discover

We make discoveries by challenging ourselves to see science and medicine differently. Ever since we opened our doors in 1988, our commitment has been to conduct the best science to make new discoveries that lead us forward. For example, after creating a proprietary gene manipulation technology, VelociGene®, to study the function of genes, we developed our VelocImmune® technology to make fully human monoclonal antibodies suitable as drug candidates.

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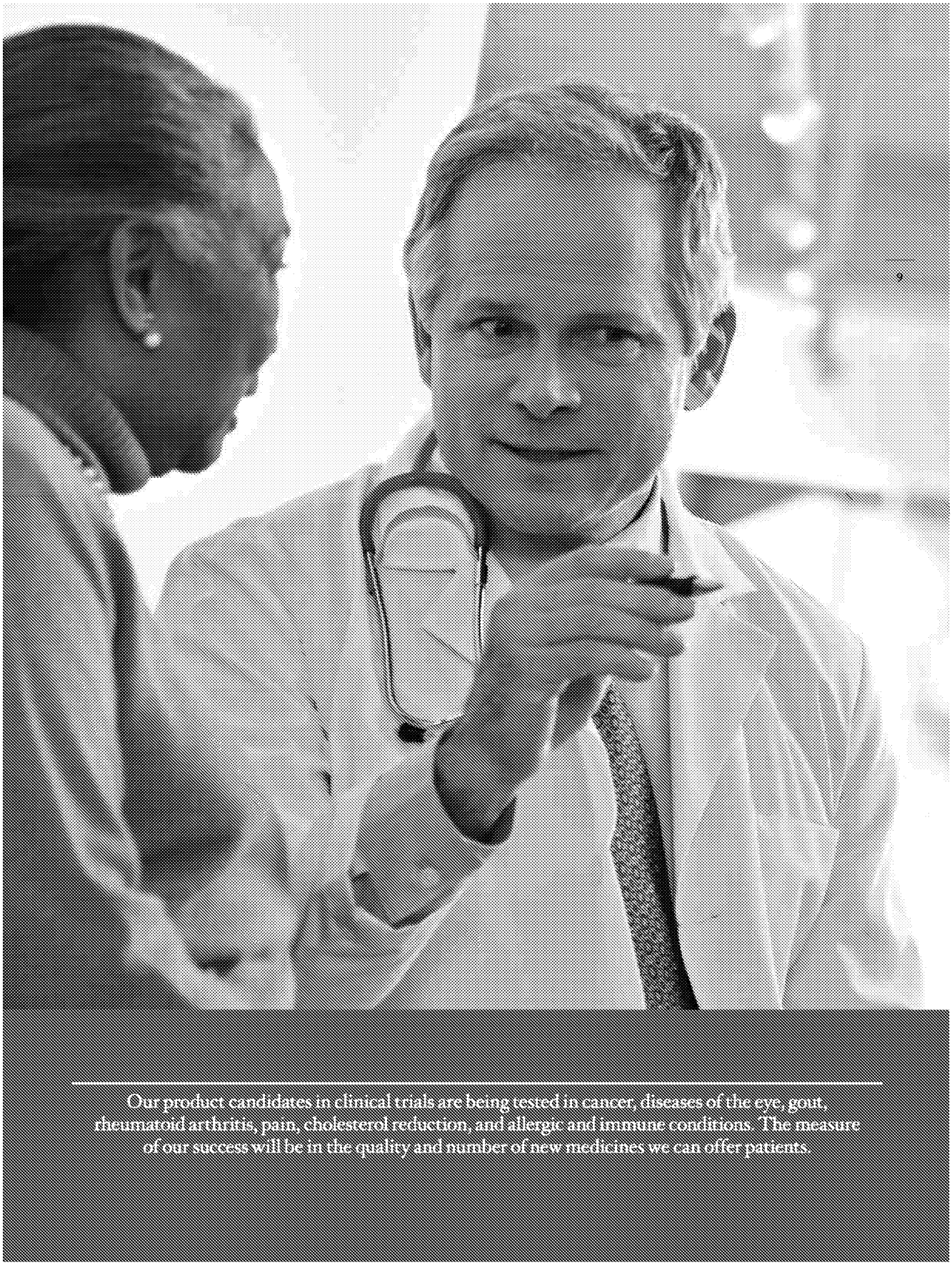
and develop

We have the full range of development capabilities, from conducting preclinical research to running large-scale clinical trials. With our collaborators, sanofi-aventis and Bayer HealthCare, we are managing clinical trials globally. We manufacture our approved product and all of our product candidates at our industrial operations facility in Rensselaer, New York, following process development in our protein science labs in Tarrytown, New York.

we're here to help patients

Our ultimate goal is to bring new drugs to market that make a difference in the lives of patients. In 2008, ARCALYST™ (rilonacept) Injection for Subcutaneous Use became our first marketed product and the first drug approved in the United States for the treatment of a rare genetic disease.



Our product candidates in clinical trials are being tested in cancer, diseases of the eye, gout, rheumatoid arthritis, pain, cholesterol reduction, and allergic and immune conditions. The measure of our success will be in the quality and number of new medicines we can offer patients.

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Dear shareholders,

During 2009, we made significant advances in our clinical programs as well as with our discovery research and preclinical development initiatives. We also expanded our antibody collaboration with sanofi-aventis to provide even greater resources to utilize our VelocImmune® human monoclonal antibody technology to grow our clinical pipeline substantially over the next eight-to-ten years. In our research labs, production facilities, and offices, there is palpable excitement about 2010 – a year that promises to be one of the most pivotal in Regeneron's history as we ramp up our expanded antibody discovery efforts and await Phase 3 clinical trial results in multiple programs.

As this annual report goes to press, 11 Phase 3 clinical studies are underway with three molecules created from our Trap fusion protein technology. These studies span a variety of diseases with unmet medical needs, including gout (four studies of our interleukin-1 inhibitor, rilonacept), retinal diseases (four studies of VEGF Trap-Eye for use in intraocular applications, in collaboration with Bayer HealthCare), and cancer (three studies of our Vascular Endothelial Growth Factor inhibitor, aflibercept [VEGF Trap], in collaboration with sanofi-aventis).

We also expect to report study results this year in multiple antibody programs partnered with sanofi-aventis. Today, most external attention is focused on our current Phase 3 programs. Soon, antibodies like REGN88 (anti-Interleukin-6 Receptor) for rheumatoid arthritis, REGN475 (anti-Nerve Growth Factor) for pain, and REGN727 (anti-PCSK9) to lower LDL cholesterol may take their place alongside our Phase 3 compounds as significant value drivers for Regeneron shareholders.

A Transformative Collaboration

The agreement to expand and extend our 2007 antibody collaboration with sanofi-aventis to discover, develop, and commercialize fully human therapeutic monoclonal antibodies promises to be truly transformative for Regeneron and ranks as one of the larger Big Pharma-biotech collaborations in the history of the biotechnology industry. Sanofi-aventis increased its annual commitment to fund discovery and preclinical research at Regeneron from $100 million to up to $160 million. This funding, originally scheduled to expire after 2012, now will extend through 2017.

As under the original 2007 collaboration terms, sanofi-aventis has an option to codevelop any antibody candidates when they are ready to enter clinical trials, and if sanofi-aventis exercises its option, it will generally pay 100 percent of clinical development costs. This provision of the agreement could generate billions of dollars of development funding for Regeneron

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George D. Yancopoulos, M.D., Ph.D.
Executive Vice President, Chief Scientific Officer, and President, Regeneron Research Laboratories

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

P. Roy Vagelos, M.D.
Chairman of the Board

above and beyond the $1.3 billion in research funding. Once antibody products from the collaboration reach the market, we and sanofi-aventis will split any resulting profits 50/50 in the United States. Outside the United States, profits will be split according to a formula under which our share will range from 35–45 percent. We will repay half of the clinical expenses funded by sanofi-aventis out of our share of the profits, subject to a cap of 10 percent of our share of the profits in any calendar quarter.

With more funding, we plan to bring an average of four to five new antibodies into clinical development each year through 2017, for a total of 30–40 new clinical-stage compounds over this time frame. During the first two years of the collaboration, Regeneron advanced five antibodies into clinical development, achieving the original goal of bringing two to three antibodies into clinical development each year. While few biotechnology companies of any size consistently bring four to five new drug candidates into clinical development each year, our track record over the first two years of the collaboration, coupled with our current robust research programs and preclinical pipeline, gives us confidence that we can meet our goal.

In the long and challenging course of drug development, more drug candidates fail than succeed — this is a fact of life in the pharmaceutical business. If we advance 30–40 high-quality antibody drug candidates into clinical development under the sanofi-aventis collaboration over the next eight years, we will have created a deep pipeline of antibody product candidates. In this way, we believe the expanded antibody collaboration changes the risk-reward profile for Regeneron shareholders. We have secured long-term funding that creates many more opportunities for success, and we have retained a sizeable profit participation in the partnered products.

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2009 – A Year of Progress

Now let's review our operational highlights over the last year.

ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS)

- ARCALYST® (rilonacept) Injection for Subcutaneous Use, our first marketed product, had shipments to distributors of $20 million in 2009. During the year, rilonacept was also approved under exceptional circumstances by the European Medicines Agency for use in CAPS.

Rilonacept in gout

- In 2009, we initiated registration-directed trials of rilonacept for the treatment of acute gout and prevention of drug-induced gout flares, following a successful Phase 2 flare prevention study, reported in 2008, in patients who initiated urate-lowering drug therapy. Gout is a painful and often debilitating form of arthritis that affects about three million Americans. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating rilonacept versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in patients with acute gout (SURGE) is evaluating treatment with rilonacept alone versus rilonacept in combination with a nonsteroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a 1,200 patient placebo-controlled safety study (RE-SURGE) of rilonacept in patients receiving urate-lowering therapy.

  Patient enrollment was completed at the end of 2009 in PRE-SURGE 1 and in February 2010 in SURGE. Initial results in both trials should be available by mid-2010. We expect results from the remaining two gout studies during the first half of 2011.

  Regeneron maintains worldwide exclusive ownership of rilonacept.

VEGF Trap-Eye in eye diseases

- In the fourth quarter of 2009, we and Bayer HealthCare completed enrollment of two Phase 3 studies of VEGF Trap-Eye (VIEW 1 and VIEW 2) in patients with the neovascular form of Age-Related Macular Degeneration (wet AMD). The studies compare VEGF Trap-Eye to Lucentis® (ranibizumab injection, a trademark of Genentech, Inc.), the standard of care in wet AMD. One year data from these studies are expected in late 2010. In addition, during 2009 we initiated two Phase 3 studies (COPERNICUS and GALILEO) in patients with Central Retinal Vein Occlusion (CRVO), with initial data from these studies expected in early 2011.
- In February 2010, we and Bayer HealthCare reported positive clinical results from a randomized, controlled Phase 2 study evaluating VEGF Trap-Eye in patients with clinically significant diabetic macular edema (DME). In each of the four treatment arms, VEGF Trap-Eye achieved the primary study endpoint, a statistically significant improvement in visual acuity over 24 weeks compared to focal laser therapy, the standard of care in DME. VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported in the study. The adverse events reported were those typically associated with intravitreal injections or the underlying disease.
- We are developing VEGF Trap-Eye in collaboration with Bayer HealthCare. Bayer HealthCare has rights to market VEGF Trap-Eye outside the United States, where we will share equally in profits from any future sales. We maintain exclusive rights to VEGF Trap-Eye in the United States.

Aflibercept (VEGF Trap) in oncology

- With our collaborator, sanofi-aventis, we are developing VEGF Trap, known as aflibercept, for the potential treatment of solid tumors. Anti-VEGF therapy with other agents has been approved for the treatment of certain cancers. In our

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program, patient enrollment is complete in Phase 3 studies in colorectal, lung and prostate cancer. In these studies, aflibercept is being evaluated in combination with the standard of care chemotherapy treatment. The primary endpoint in each study is overall survival, measured when a prespecified number of deaths have occurred. In the VELOUR study evaluating aflibercept as a second line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan), an interim analysis is expected in the second half of 2010, with final results in the second half of 2011. We currently anticipate completion of the VITAL trial evaluating aflibercept as a second line treatment for non-small cell lung cancer in combination with docetaxel during the first half of 2011. We also anticipate that an interim analysis of the VENICE trial evaluating aflibercept as a first line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone will be conducted during the first half of 2011, with final results available in 2012.

- In June 2009, we reported results of a Phase 2 study of aflibercept in women with advanced ovarian cancer who had recurrent symptomatic malignant ascites (SMA), an abnormal buildup of fluid in the abdominal cavity. Aflibercept was clinically active in this setting and met the primary study endpoint. Nonetheless, after reviewing the study data, we and sanofi-aventis concluded that it was difficult to definitively assess the overall clinical benefit that might be derived from treatment in the real-world clinical practice setting and, therefore, that the data were not sufficient to submit for regulatory approval in the SMA setting.
- Clinical development is not without its challenges. In September 2009, we and sanofi-aventis announced the discontinuation of a Phase 3 clinical trial evaluating aflibercept plus gemcitabine for the first line treatment of metastatic pancreatic cancer after the Independent Data Monitoring Committee for the trial determined that aflibercept would not show meaningful improvement over current therapy.

REGN475 for pain

- This antibody binds to nerve growth factor (NGF), a novel target for pain indications. During 2009, we and sanofi-aventis completed a Phase 1 study and initiated Phase 2 studies in osteoarthritis of the knee and other pain indications. We expect initial Phase 2 results this year. A number of pharmaceutical companies also have anti-NGF product candidates in clinical development.

REGN88 for rheumatoid arthritis

- This antibody binds to the interleukin-6 (IL-6) receptor, blocking its ligand, IL-6. During 2009, we and sanofi-aventis completed several Phase 1 studies. In the first quarter of 2010, we began a Phase 2/3 study in rheumatoid arthritis, for which another IL-6 antibody recently has been approved, and a Phase 2 study in ankylosing spondylitis, a form of arthritis that primarily affects the spine.

REGN421 for advanced malignancies

- This antibody binds to Delta-like ligand-4 (Dll4), a novel anti-angiogenesis target. In 2009, we and sanofi-aventis continued to study REGN421 in a Phase 1 study in patients with advanced malignancies.

REGN727 for cholesterol reduction

- This antibody binds to PCSK9, a novel target for LDL cholesterol reduction. We and sanofi-aventis initiated a Phase 1 study during the fourth quarter of 2009.

REGN668 for allergic and immune conditions

- This antibody binds to the interleukin-4 receptor, a target implicated in allergic and immune conditions. We and sanofi-aventis initiated a Phase 1 study during the fourth quarter of 2009.

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Industrial Operations

At our manufacturing facilities in Rensselaer, New York, our industrial operations are on track to double our production capacity to 54,000 liters by the end of 2010. Each of our drug candidates in clinical development, as well as our marketed product, ARCALYST® (rilonacept), is manufactured at our Rensselaer site. We believe that our in-house process development and large-scale manufacturing capabilities represent critical competencies for a biopharmaceutical company.

New lab and office space

To accommodate our growth, most employees moved last fall into two new buildings constructed for us on the Tarrytown, New York campus we have occupied since 1989. The state-of-the-art facility (featured in the photography on the preceding pages) makes ample use of glass and natural light to create a feeling of openness and collaboration, sustainable materials such as bamboo flooring, and energy-saving features including heat-reflecting white roofs. A third new building with identical design is under construction next door and is slated for occupancy in 2011.

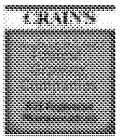
Recruiting Talent

Clearly, there's a lot of momentum at Regeneron, and our early and late-stage clinical pipeline has never been so full. To meet our ambitious objectives under the sanofi-aventis antibody collaboration, we are recruiting new talent at Regeneron. We employed more than 1,000 people at the start of 2010 and aim to hire approximately 500 more staff by the end of the year, many to support the research, development, and production commitments under our antibody collaboration. Hiring so many scientists, manufacturing personnel, and other staff to support our expanding pipeline will be a challenge, but we are experienced in meeting such challenges: In 2008–09, we increased staff by more than 50 percent to meet the deliverables of the initial antibody collaboration initiated in late 2007, and we have already recruited 185 new employees in the first quarter of 2010.

Meeting our recruitment targets while preserving our science-driven culture is an important goal. With so much going on at the company, and with many Big Pharma and small biotechs reducing staff, we are well positioned to continue to attract top talent. A major advantage in our recruiting is the energy and passion of our people, which are visible to job candidates and other visitors to our operations in Tarrytown and Rensselaer.

We are pleased that Regeneron has been recognized over the last year with several awards. *The Scientist* selected us for the third year in a row as one of the best places to work for scientists in biotechnology. *Fast Company* cited us one of the most innovative companies in the world. *Forbes.com* named us among its 100 most trust worthy companies that have "consistently demonstrated transparent and conservative accounting practices and solid corporate governance and management." These and other recognitions are featured below.

We were recognized over the last year for the following achievements:



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Our Financial Position Is Strong, Too

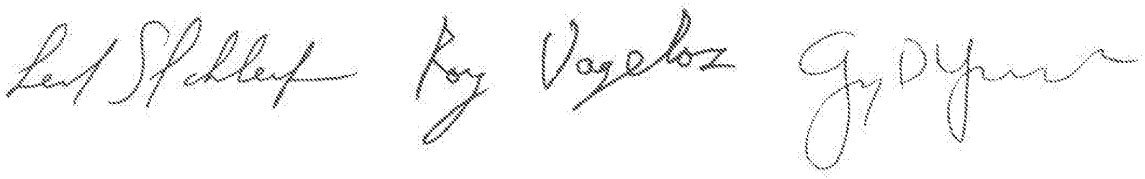
In 2009, our revenues were $379 million compared to $238 million in 2008. In both years, a majority of revenues were reimbursements from sanofi-aventis and Bayer HealthCare for our spending on collaboration programs. Including R&D expenditures on collaboration programs by sanofi-aventis and Bayer HealthCare, total 2009 R&D spending on our programs was over $570 million, compared to approximately $400 million in 2008.

Our cash usage was $146 million in 2009 compared to $126 million in 2008. These figures exclude proceeds from stock option exercises and, in 2008, repayment of convertible debt. Our relatively modest cash burn in relation to the size of our R&D programs is due to our collaborations with sanofi-aventis and Bayer HealthCare. We refer to the difference between our cash burn and total R&D expenditures as "research leverage." We believe this provides strategic value, as the structure of our collaborations makes it possible to conduct R&D on a scale much greater than we could support on our own. We expect total R&D spending in 2010, including spending by sanofi-aventis and Bayer HealthCare on collaboration programs, to be over $700 million.

Looking Ahead

As we look ahead, we can say that Regeneron entered 2010 from a position of strength. We are fueled by a productive and energized first-class research and development organization that has built a robust clinical pipeline. We have drug candidates in all stages of development, and these address a broad range of therapeutic indications. Strong science and R&D programs are further bolstered by productive collaborations and a healthy balance sheet. Regeneron has no debt (other than lease obligations) and at March 31, 2010 had $414 million in cash and investments.

All of these opportunities would not be possible without the tireless commitment of our employees, our collaborators, and our clinical investigators; the courageous participation of the patients in our clinical studies; and the support from you, our shareholders. We thank you all as we continue to do cutting-edge science and strive to bring better medicines to patients worldwide.



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financial information

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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, 2009

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 $1,355,426,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2009, 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 12, 2010:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	2,211,698
Common Stock, $.001 par value	79,441,680

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2010 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 65 to 68 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 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 eight product candidates in clinical development, including three that are in late-stage (Phase 3) clinical development. Our late stage programs are rilonacept, which is being developed for the prevention and treatment of gout-related flares; VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain; 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; REGN727, an antibody to PCSK9, which is being developed for low density lipoprotein (LDL) cholesterol reduction; and REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed for certain allergic and immune conditions. All five of our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. 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 (*VelociMab*™) may then be utilized to design and produce new product candidates directed against the disease target. Our five 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 over the next eight years. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

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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 $20.0 million of ARCALYST® (rilonacept) to our distributors in 2009, compared to $10.7 million in 2008. We own worldwide rights to ARCALYST.

In October 2009, rilonacept was approved under exceptional circumstances by the European Medicines Agency (EMEA) for the treatment of CAPS with severe symptoms in adults and children aged 12 years and older. Such authorizations are permissible for products for which a company can demonstrate that comprehensive data cannot be provided, for example, because of the rarity of the condition. Each year, we will need to provide for review by the EMEA any new or follow-up information that may become available. Rilonacept is not currently marketed in the European Union.

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 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 *CIASI*) 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.

Clinical Programs:

*1. **Rilonacept – Inflammatory Diseases***

We are evaluating rilonacept in gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation. In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of rilonacept versus placebo in the prevention of gout flares induced by the initiation of urate-lowering drug therapy. 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 rilonacept (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 rilonacept, 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 rilonacept and no serious drug-related adverse events were reported.

Results from this study after the first 16 weeks of urate-lowering therapy were reported at the annual meeting of the European League Against Rheumatism (EULAR) in June 2009. Through 16 weeks, the mean number of flares per patient was 0.93 with placebo and 0.22 with rilonacept (p=0.0036). In the first 16 weeks of treatment, 47.6% of patients treated with placebo experienced a gout flare and, of those, 55.0% had more than one flare. Among patients treated with rilonacept, 22.0% experienced a gout flare (p=0.0209 versus placebo) and none had more than one flare. Adverse events after 16 weeks of treatment were similar to those reported after 12 weeks with the most frequently reported categories being infection and musculoskeletal complaints.

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.

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During the first quarter of 2009, we initiated a Phase 3 clinical development program with rilonacept for the treatment of gout. The program includes four clinical trials. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating rilonacept versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) is evaluating treatment with rilonacept alone versus rilonacept in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a placebo-controlled safety study (RE-SURGE) of rilonacept in patients receiving urate-lowering therapy. SURGE and PRE-SURGE 1 are fully enrolled. We expect to report initial data from SURGE and PRE-SURGE 1 during the first half of 2010 and from PRE-SURGE 2 and RE-SURGE during the first half of 2011.

Royalty Agreement with Novartis Pharma AG

In June 2009, we entered into a royalty agreement with Novartis Pharma AG that replaced a previous collaboration and license agreement. Under this agreement, we are entitled to receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1β antibody. We waived our right to opt-in to the development and commercialization of canakinumab. Canakinumab is approved to treat Cryopyrin-Associated Periodic Syndrome (CAPS) and is in development for chronic gout, type 2 diabetes, and a number of other inflammatory diseases.

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 are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). 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. We and Bayer HealthCare also initiated a Phase 3 program in central retinal vein occlusion (CRVO) in July 2009. In connection with the dosing of the first patient in a Phase 3 study in CRVO, we received a $20.0 million milestone payment from Bayer HealthCare.

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 Lucentis® (ranibizumab injection), marketed by 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 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 doses) compared with Lucentis (Genentech) 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 will be evaluated in the second year of the studies. VIEW 1 and VIEW 2 were fully enrolled in 2009, and initial data are expected in late 2010.

We and Bayer HealthCare have conducted 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. These one-year study results were reported at the 2008 annual meeting of the Retina Society. In this double-masked Phase 2 trial, known as CLEAR-IT 2, 157 patients were initially treated for three months with VEGF Trap-Eye: two groups received monthly doses of 0.5 or 2.0 mg (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg (at baseline and week 12). Following the initial three-month fixed-dosing phase, patients continued to receive VEGF Trap-Eye at the same dose on a PRN dosing schedule through one year, based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria.

In this Phase 2 study, patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 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. After

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week 12 to week 52 in the 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.

All patients who completed the one year CLEAR-IT 2 study were eligible to participate in an extension stage of the study. Twenty-four-month results of the extension stage were presented in October 2009 at the 2009 American Academy of Ophthalmology meeting. After receiving VEGF Trap-Eye for one year, the 117 patients who elected to enter the extension stage were dosed on a 2.0 mg PRN basis, irrespective of the dose at which they were treated earlier in the study. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters (p<0.0001 versus baseline) at the three-month primary endpoint of the original Phase 2 study, 8.4 letters (p<0.0001 versus baseline) at one year, and 6.1 letters (p<0.0001 versus baseline) at month 12 of the extension stage. Thus, after 24 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 4.6 injections over the 21-month PRN dosing phase that extended from month three to month 24. The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

The DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye dosing regimens versus laser treatment. A total of 240 patients with clinically significant DME with central macular involvement were randomized to five groups. VEGF Trap-Eye achieved the primary endpoint of the study, a statistically significant improvement in visual acuity compared to focal laser therapy, the standard of care in DME. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. 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 in the study. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results will be available later in 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of central retinal vein occlusion (CRVO), another cause of blindness. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 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 will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. Enrollment in the COPERNICUS study began during the third quarter of 2009, and enrollment in the GALILEO study began in October 2009. Initial data are anticipated in early 2011.

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 CRVO. 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

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of the first patient in a Phase 3 study of VEGF Trap-Eye in wet AMD. In July 2009, we 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 CRVO. We can earn up to $70 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. *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), VEGF-B, 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 three Phase 3 trials that combine aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial (called 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 metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen independent prostate cancer in combination with docetaxel/prednisone. All three trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. VITAL and VENICE are fully enrolled, and the VELOUR study is approximately 95% enrolled. In addition, a Phase 2 study (called AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with FOLFOX (folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin) is approximately 75% enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical 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 prespecified number of events have occurred in each trial. Based on current enrollment and event rates, (i) an interim analysis of VELOUR is expected to be conducted by an IDMC in the second half of 2010, (ii) final results are anticipated in the first half of 2011 from the VITAL study and in the second half of 2011 from the VELOUR study, and (iii) an interim analysis of VENICE is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012.

A fourth Phase 3 trial (VANILLA) that was evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued in September 2009 following a planned interim efficacy analysis by that study's IDMC. The IDMC determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine in this study. The types and frequencies of adverse events reported in the combination arm with aflibercept were generally as anticipated.

During 2009, summary results were reported for a randomized, placebo-controlled Phase 2 single-agent study of aflibercept in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA), an abnormal build-up of fluid in the abdominal cavity. Patients receiving aflibercept experienced a statistically significant improvement (55 days with aflibercept as compared to 23 days for patients receiving placebo ($p=0.0019$)) in the primary study endpoint, mean time to first repeat paracentesis (removal of fluid from the abdominal cavity), versus placebo control. There was a statistically similar incidence of deaths in both treatment groups. Four fatal events were assessed by the investigators as aflibercept treatment related. The types and frequencies of adverse events reported with aflibercept in this study were generally consistent with those reported in clinical studies with other anti-VEGF therapies in AOC patients. Although the study demonstrated that aflibercept is a clinically active agent in this setting, given the small number of patients enrolled in this study and their fragile health status, we and sanofi-aventis concluded that it was difficult to definitively assess the overall clinical benefit that might be derived from treatment in the real-world clinical practice setting and, therefore, the data were not sufficient to submit for regulatory approval in the SMA indication.

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Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) 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 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 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. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

REGN475 is a fully human monoclonal antibody to NGF generated using our *VelocImmune*® technology. 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-4/5, or BDNF.

In the third quarter of 2009, we began a Phase 2 double-blind, placebo-controlled, dose-ranging, proof-of-concept study of REGN475 in persons with osteoarthritis of the knee. Preliminary data from that study are expected in the first half of 2010. Additionally, four Phase 2 proof-of-concept studies in other pain indications (sciatica, vertebral fracture, chronic pancreatitis, and thermal injury) were initiated in late 2009 and early 2010. REGN475 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), tocilizumab, developed by Roche, 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 is 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. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN421 (Anti-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 specifically 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 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. 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 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

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7. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase substilisin/kexin type 9) is a protein that binds to LDLR, which prevents LDLR from binding to LDL and removes it from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. We used our *VelocImmune®* technology to derive a fully human monoclonal antibody called REGN727 that is designed to bind to PCSK9 and prevent it from inhibiting LDLR. REGN727 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

8. REGN668 (Anti-IL4R Antibody) for allergic and immune conditions

Interleukin-4 receptor (IL4Ra) 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 antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis. REGN668 is a fully human *VelocImmune* antibody that is designed to bind to IL4R. REGN668 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

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 specific secreted proteins can have clinical benefit.

Our 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® (rilonacept), 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 and it is used for discovering, developing, and producing fully human monoclonal antibodies.

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, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out 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 pre-clinical development and toxicology programs, *VelociGene* offers the

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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, the VelociMice 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. 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 $175 million of research from the collaboration's inception through December 31, 2009. In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now 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 are not satisfied. In addition, sanofi-aventis will fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities. As under the original 2007 agreement, 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. 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 over the next eight years.

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. To date, sanofi-aventis has opted into the development of five antibody candidates. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development 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 will be 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 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.

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AstraZeneca U K L imited. 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 $20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, and 2009. AstraZeneca is required to make up to three additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the next annual payment in the first quarter of 2010. 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 Pharma Inc. 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 $20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, and 2009. Astellas is required to make up to three additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the next annual payment in the second quarter of 2010. 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

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, we are entitled to receive a minimum of $25.3 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.

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® (rilonacept) 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. If we receive regulatory approval to market and sell additional products in the United States or in other countries, we may either expand our commercial organization or rely on third party product licensees or service providers.

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 27,500 liters of cell culture capacity at these facilities and have plans to increase our manufacturing capacity to approximately 54,000 liters in 2010. Up to $30 million of agreed-upon costs related to this expansion will be funded by sanofi-aventis under the terms of our amended antibody collaboration. At December 31, 2009, we employed 278 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2009.

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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., Eli Lilly and Company, Abbott, 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. 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 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). In 2009, Novartis received regulatory approval in the U.S. and Europe for canakinumab (Ilaris®), a fully human anti-interleukin-IL1β antibody, for the treatment of CAPS. Canakinumab is also in development for chronic gout and a number of other inflammatory diseases. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is significantly more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. In addition, there are both small molecules and antibodies in development by other third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly 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 and/or commercialization of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYST.

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 (Genentech) 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 and VEGF receptors, and through the 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, a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin® (bevacizumab). 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 (NEI) initiated a Phase 3 trial to compare Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. Data from this NEI study are expected to be published in 2011. 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.

Aflibercept (VEGF Trap). 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.

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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, Pfizer, Imclone/Eli Lilly, AstraZeneca, and GlaxoSmithKline. Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Pfizer and Onyx (together with its partner Bayer Healthcare) 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, MedImmune, LLC (a subsidiary of AstraZeneca), Amgen, Biogen Idec, Inc., Novartis, Roche, Genentech, 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.

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. The Pfizer antibody against NGF is in Phase 3 clinical trials for the treatment of pain due to osteoarthritis. Roche is marketing an antibody against the interleukin-6 receptor (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 interleukin-4 in clinical development. Amgen previously had an antibody against the interleukin-4 receptor in clinical development for the treatment of asthma. We believe that several companies, including Amgen, have development programs for antibodies against PCSK9.

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.

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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. As of December 31, 2009, we held an ownership interest in a total of approximately 180 issued patents in the United States and over 750 issued patents in foreign countries with respect to our products and technologies. In addition, we held 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® (rilonacept), and our product candidates in clinical development. These patents cover the proteins and DNA encoding the proteins, manufacturing patents, method of use patents, pharmaceutical compositions, as well as various methods of using the products. For each of ARCALYST and our late-stage clinical candidates, aflibercept (VEGF Trap) and VEGF Trap-Eye, these patents generally expire between 2020 and 2026. 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 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.

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 "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

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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.

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, (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, 2009, we had 1,029 full-time employees, of whom 192 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.

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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.

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, 2009, we had a cumulative loss of $941.1 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, 2009, cash, cash equivalents, restricted cash, and marketable securities totaled $390.0 million and represented 53% 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 and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled $181.3 million at December 31, 2009, are carried at fair value, and the unrealized gains and losses are included in other accumulated

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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 $5.9 million, $2.5 million and $0.1 million in 2007, 2008, and 2009, respectively. 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.

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 testing aflibercept, VEGF Trap-Eye, and rilonacept 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 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.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of Central Retinal Vein Occlusion (CRVO). Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis (Genentech). 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. VEGF Trap-Eye has not been previously studied in CRVO.

Rilonacept is in Phase 3 clinical trials for two different gout indications – the prevention of gout flares in patients initiating urate-lowering drug therapy and acute gout. We do not have proof of concept data from Phase 2 clinical trials that rilonacept will be safe or effective in the acute gout setting. Although we reported positive Phase 2 proof of concept data from a small number of patients initiating urate-lowering drug therapy, there is a risk that the results of the larger Phase 3 trials of rilonacept in patients initiating urate-lowering drug therapy will differ from the previously reported Phase 2 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.

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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 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.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or 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 harm 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 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.

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,

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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 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® (rilonacept) 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), marketed by Biovitrum, Enbrel® (etanercept), marketed by Amgen and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by 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 (Biovitrum), 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.

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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 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.

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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® (rilonacept) 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 and the EMEA 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 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 Good Clinical Practice regulations (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.

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.

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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 a reduction in sales.

We and our third party providers are required to maintain compliance with current Good Manufacturing Practice, or 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 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 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 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.

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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 and also at the federal level. 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 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, 2009, 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 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;

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- 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 current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and current pending legislation which would 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 $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 REGN88, REGN421, REGN475, REGN727, and REGN668 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.

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

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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 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 with applicable Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development 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

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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, 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 for ARCALYST and our product candidates at our manufacturing facilities 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, fire, natural disasters, or other problems at the facilities.

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, 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, 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 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

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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 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 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. 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.

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, 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 and Onyx, (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.

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), DME, and other eye indications. Lucentis (Genentech) 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 and VEGF receptors,

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and through the 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, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin. 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. 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 (Amgen and Wyeth), Remicade (Centocor), Humira® (adalimumab), marketed by Abbott, and Simponi™ (golimumab), marketed by Centocor, and the IL-1 receptor antagonist Kineret (Biovitrum), and other marketed therapies makes it more difficult to successfully develop and commercialize rilonacept in other indications. This is one of the reasons we discontinued the development of rilonacept in adult rheumatoid arthritis. In addition, even if rilonacept 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 rilonacept, 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 received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. For example, Novartis' IL-1 antibody 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 impair our ability to successfully commercialize ARCALYST.

We have plans to develop rilonacept for the treatment of certain gout indications. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. Novartis' IL-1 antibody is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over rilonacept in gout by some physicians, which would make it difficult for us to successfully commercialize rilonacept in that disease.

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 rilonacept 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 rilonacept 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

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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. Payers may especially 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 recently 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. 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.

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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® (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, 2009, our four largest shareholders plus Leonard Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 41.6% 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, 2009. As of December 31, 2009, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.8% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 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, 2009, holders of Class A Stock held 22.2% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, including 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

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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, 2009:

- our current executive officers and directors beneficially owned 14.0% 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, 2009, and 28.5% 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, 2009; and
- our four largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 41.6% 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, 2009. In addition, these five shareholders held 48.5% 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, 2009.

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 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."*

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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.

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 537,100 square feet of laboratory and office facilities, including approximately 406,200 square feet of space that we currently occupy and approximately 130,900 square feet of additional new space that is under construction and expected to be completed in mid-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 290,400 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 that is under construction will commence in January 2011 and additional charges for utilities, taxes and operating expenses commenced in January 2010.

In December 2009, we leased, on a short-term basis, approximately 16,700 square feet of laboratory and office space at our current Tarrytown location while construction is completed on our additional new facilities, as described above. We expect to lease this space through May 2011. We also entered into a separate agreement in December 2009 to lease approximately 6,600 additional square feet of laboratory and office space at our current Tarrytown location in facilities that are now under construction and expected to be completed in mid-2010. 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. Monthly lease payments on this additional space that is under construction are expected to commence in June 2010.

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 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]	389,500	June, 2024	$1,115,000	Three 5-year terms
Tarrytown, New York[3]	130,900	June, 2024	—	Three 5-year terms
Tarrytown, New York[2]	16,700	May, 2011	$ 7,900	None
Tarrytown, New York[4]	6,600	August, 2011	—	Incorporate into main Tarrytown lease
Bridgewater, New Jersey[5]	14,100	July 2011	$ 21,700	None

(1) Excludes additional charges for utilities, real estate taxes, and operating expenses, as defined, included in our rent.

(2) Represents space currently occupied in Tarrytown, New York as described above.

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(3) Represents space currently under construction. Rental payments will commence in January 2011.

(4) Represents space currently under construction. Rental payments will commence in June 2010.

(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.

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, 2009.

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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
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
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

As of February 12, 2010, there were 462 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 2010 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Report on Form 10-K.

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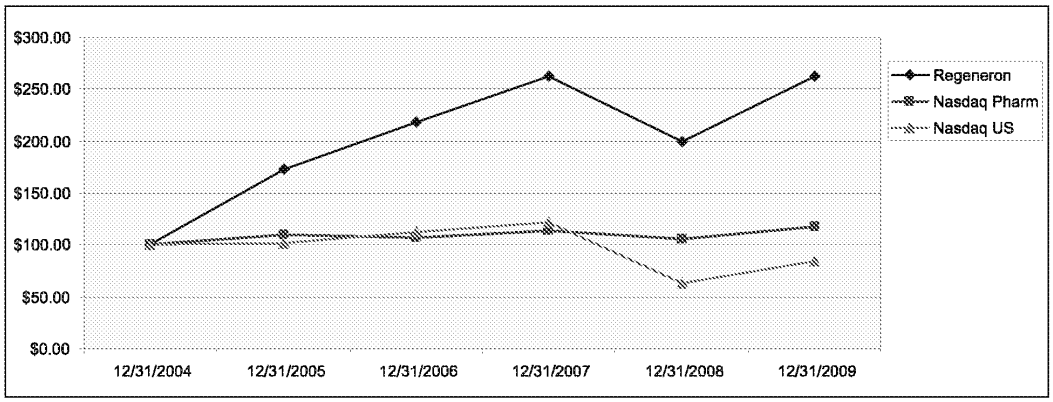
STOCK PERFORMANCE GRAPH

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, 2004 through December 31, 2009. The comparison assumes that $100 was invested on December 31, 2004 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.



	12/31/2004	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009
Regeneron	$100.00	$172.64	$217.92	$262.21	$199.35	$262.54
Nasdaq Pharm	100.00	110.12	107.79	113.36	105.48	118.52
Nasdaq US	100.00	102.13	112.19	121.68	62.73	84.28

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ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2009, 2008, and 2007 and at December 31, 2009 and 2008 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, 2006 and 2005 and at December 31, 2007, 2006, and 2005 are derived from our audited financial statements not included in this report.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
		*Revised**	*Revised**		
	(In thousands, except per share data)				
Statement of Operations Data					
Revenues					
Collaboration revenue	$314,457	$185,138	$ 87,648	$ 47,763	$ 49,372
Technology licensing	40,013	40,000	28,421		
Contract manufacturing				12,311	13,746
Net product sales	18,364	6,249			
Contract research and other	6,434	7,070	8,955	3,373	3,075
	379,268	238,457	125,024	63,447	66,193
Expenses					
Research and development	398,762	274,903	202,468	137,064	155,581
Contract manufacturing				8,146	9,557
Selling, general, and administrative	52,923	48,880	37,929	25,892	25,476
Cost of goods sold	1,686	923			
	453,371	324,706	240,397	171,102	190,614
Income (loss) from operations	(74,103)	(86,249)	(115,373)	(107,655)	(124,421)
Other income (expense)					
Other contract income					30,640
Investment income	4,488	18,161	20,897	16,548	10,381
Interest expense	(2,337)	(7,752)	(12,043)	(12,043)	(12,046)
Loss on early extinguishment of debt		(938)			
	2,151	9,471	8,854	4,505	28,975
Net loss before income tax expense and cumulative effect of a change in accounting principle	(71,952)	(76,778)	(106,519)	(103,150)	(95,446)
Income tax (benefit) expense	(4,122)	2,351			
Net loss before cumulative effect of a change in accounting principle	(67,830)	(79,129)	(106,519)	(103,150)	(95,446)
Cumulative effect of a change in accounting principle related to share-based payments				813	
Net loss	$ (67,830)	$ (79,129)	$(106,519)	$(102,337)	$ (95,446)
Net loss per share, basic and diluted:					
Net loss before cumulative effect of a change in accounting principle	$ (0.85)	$ (1.00)	$ (1.61)	$ (1.78)	$ (1.71)
Cumulative effect of a change in accounting principle related to share-based payments				0.01	
Net loss	$ (0.85)	$ (1.00)	$ (1.61)	$ (1.77)	$ (1.71)

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	At December 31,				
	2009	2008	2007	2006	2005
		*Revised**	*Revised**		
			(In thousands)		
Balance Sheet Data					
Cash, cash equivalents, restricted cash, and marketable securities (current and non-current)	$390,010	$527,461	$ 846,279	$ 522,859	$ 316,654
Total assets	741,202	724,220	957,881	585,090	423,501
Notes payable - current portion			200,000		
Notes payable - long-term portion				200,000	200,000
Facility lease obligations	109,022	54,182	21,623		
Stockholders' equity	396,762	421,514	459,348	216,624	114,002

* We have revised our financial statements at December 31, 2008 and 2007 and for the years ended December 31, 2008 and 2007 in connection with the application of authoritative guidance issued by the Financial Accounting Standards Board (FASB) to our December 2006 lease, as amended, of laboratory and office facilities in Tarrytown, New York. The revisions, and a description of the basis for the revisions, are more fully described in Note 11 to our audited financial statements included elsewhere in this report.

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 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 eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are rilonacept, which is being developed for the prevention and treatment of gout-related flares; VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with sanofi-aventis. Our earlier stage clinical programs are REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain; 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; REGN727, an antibody to PCSK9, which is being developed for LDL cholesterol reduction; and REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed for certain allergic and immune conditions. All five of our early stage clinical programs are fully human antibodies that are being developed 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, cardiovascular diseases, and infectious 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.

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From inception on January 8, 1988 through December 31, 2009, we had a cumulative loss of $941.1 million. In the absence of significant revenues from the commercialization of ARCALYST® (rilonacept) 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 rilonacept in other indications; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering 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 collaborators, including sanofi-aventis, (ii) funding from our collaborators and licensees in the form of up-front and milestone payments, research progress payments, and payments for our research and development activities, and (iii) a private placement of convertible debt, which was repaid in full during 2008.

In 2009, our research and development expenses totaled $398.8 million. In 2010, we expect these expenses to increase substantially as we continue to expand our research and preclinical and clinical development activities, primarily in connection with our antibody collaboration with sanofi-aventis.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2009 was 980 compared with 810 in 2008 and 627 in 2007. In 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 2007 our average headcount increased primarily to support our expanded development programs for VEGF Trap-Eye and rilonacept and our plans to move our first antibody candidate into clinical trials. In 2010, we expect our average headcount to increase to approximately 1,350-1,400, 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.

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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 2009 and 2010 to date were, and plans for the remainder of 2010 are, as follows:

Clinical Program	2009 and 2010 Events to Date	2010 Plans
Rilonacept (also known as IL-1 Trap)	• Initiated patient enrollment in two Phase 3 trials (PRE-SURGE 1 and PRE-SURGE 2) evaluating rilonacept in the prevention of gout flares associated with the initiation of urate-lowering drug therapy; completed patient enrollment in the PRE-SURGE 1 study • Initiated and completed patient enrollment in a Phase 3 study (SURGE) evaluating rilonacept in the treatment of acute gout flares	• Report data from SURGE and PRE-SURGE 1 during the first half of 2010 • Complete patient enrollment of the remaining Phase 3 studies in gout
VEGF Trap-Eye (intravitreal injection)	• Completed patient enrollment in the Phase 3 wet AMD program (VIEW 1 and VIEW 2) • Initiated a Phase 3 CRVO program • Reported results from the Phase 2 DME trial	• Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010 • Complete patient enrollment of the Phase 3 CRVO trials
Aflibercept (VEGF Trap – Oncology)	• Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer and prostate cancer • Initiated a Phase 2 1st line study in metastatic colorectal cancer in combination with chemotherapy • Reported results of a Phase 2 single-agent study in symptomatic malignant ascites (SMA) • Discontinued a Phase 3 study in metastatic pancreatic cancer in combination with chemotherapy	• Complete patient enrollment in the Phase 3 study in colorectal cancer • During the second half of 2010, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study in colorectal cancer
Monoclonal Antibodies	• REGN475: Initiated a Phase 1 trial in healthy volunteers, a dose-ranging, proof-of-concept study in osteoarthritis of the knee, and additional proof-of-concept studies in pain associated with sciatica, vertebral fracture, chronic pancreatitis, and thermal injury • REGN88: Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis and a Phase 2 dose-ranging study in ankylosing spondylitis • REGN421: Initiated a Phase 1 trial in oncology • REGN727: Initiated a Phase 1 program in healthy volunteers • REGN668: Initiated a Phase 1 program in healthy volunteers	• REGN475: Report data from the study in osteoarthritis of the knee during the first half of 2010 and from the study in sciatica during the second half of 2010 • REGN727: Report proof-of-concept data from the Phase 1 program and initiate a Phase 2 program for LDL cholesterol reduction • REGN668: Initiate a Phase 2 program in the treatment of a chronic allergic condition • REGN88: Report data from a Phase 1 trial in rheumatoid arthritis • Advance additional antibody candidate(s) into clinical development

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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

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.

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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, during the fourth quarter of 2008, we extended our estimated performance period in connection with the up-front and non-substantive 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 collaboration 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. In addition, in connection with amendments to expand and extend our antibody collaboration with sanofi-aventis, during the fourth quarter of 2009, we extended our estimated performance period related to the up-front payment previously received from sanofi-aventis pursuant to the companies' antibody collaboration. The effect of this change in estimate resulted in the recognition of $0.6 million less in collaboration revenue in the fourth quarter of 2009, compared to amounts recognized in each of the prior three quarters of 2009. 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. 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. Since we 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 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.

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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, 2009, 2008, or 2007.

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.

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 and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed 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.

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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.

As a result of our quarterly reviews of our marketable securities portfolio, during 2009, 2008, and 2007 we recorded charges for other-than-temporary impairment of our marketable securities totaling $0.1 million, $2.5 million, and $5.9 million, respectively. The current economic environment and the deterioration in the credit quality of issuers of securities that we hold increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the 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, 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® (rilonacept) sales, partially 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

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists 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.

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Sanofi-aventis Collaboration Revenue *(In millions)*	Years ended December 31, 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 earn from Bayer HealthCare, as detailed below, consists 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 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 *(In millions)*	Years ended December 31, 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

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

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to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO. In July 2009, we received a $20.0 million substantive performance milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO, 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 are 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® (rilonacept) net product sales for which both the right of return no longer exists and rebates can 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 are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2009 and 2008 include a total of $31.3 million and $32.5 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, 2009		
Expenses	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
(In millions)			
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

	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	$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

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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 $398.4 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	Year Ended December 31, 2009	2008	Increase
(In millions)			
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 preclinical 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) rilonacept, 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 rilonacept and monoclonal antibodies, partially offset by lower costs related to manufacturing aflibercept clinical supplies. 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 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.

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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, 2009	2008	Increase (Decrease)
(In millions)			
Rilonacept	$ 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

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 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 rilonacept, 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 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We shipped $20.0 million and $10.7 million of ARCALYST to our U.S. distributors in 2009 and 2008, respectively.

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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® (rilonacept). These increases were partially 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. 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 included in cost of goods sold when revenue is recognized from the sale of those supplies 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.

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 partially offset by realized gains of $0.2 million and $1.2 million, respectively, on sales of marketable securities during the year.

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 (Benefit) Expense

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 allows 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 allows 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.

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Years Ended December 31, 2008 and 2007

Net Loss

Regeneron reported a net loss of $79.1 million, or $1.00 per share (basic and diluted), for the year ended December 31, 2008, compared to a net loss of $106.5 million, or $1.61 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 in 2008 and 2007 consist of the following:

(In millions)	2008	2007
Collaboration revenue		
Sanofi-aventis	$154.0	$ 51.7
Bayer HealthCare	31.2	35.9
Total collaboration revenue	185.2	87.6
Technology licensing revenue	40.0	28.4
Net product sales	6.3	
Contract research and other revenue	7.0	9.0
Total revenue	$238.5	$125.0

Sanofi-Aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists 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	**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 collaboration 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.

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In August 2008, we entered into a separate *VelociGene*® agreement with sanofi-aventis. In 2008, we recognized $1.2 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists 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 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

	Years ended December 31,	
Bayer HealthCare Collaboration Revenue	**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 collaboration 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 and $20.0 million milestone payments from Bayer HealthCare are being recognized as collaboration revenue 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 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, 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 catch-up 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.

Technology Licensing Revenue

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. In 2008 and 2007, we recognized $40.0 million and $28.4 million, respectively, of technology licensing revenue related to these agreements.

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Net Product Sales

In 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.

Contract Research and Other Revenue

Contract research and other revenue in 2008 and 2007 included $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.

Expenses

Total operating expenses increased to $324.7 million in 2008 from $240.4 million in 2007. Our average headcount in 2008 increased to 810 from 627 in 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, 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	$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

	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	$186.3	$16.2	$202.5
Selling, general, and administrative	26.0	11.9	37.9
Total operating expenses	$212.3	$28.1	$240.4

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.

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Research and Development Expenses

Research and development expenses increased to $274.9 million in 2008 from $202.5 million in 2007. The following table summarizes the major categories of our research and development expenses in 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	30.5	23.5	7.0
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses[3]	30.0	10.6	19.4
Total research and development	$274.9	$202.5	$72.4

(1) Includes $16.7 million and $13.2 million of Non-cash Compensation Expense in 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 in 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. 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, which includes our VIEW 1 trial in wet AMD, (ii) 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 rilonacept 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 and expanded research and development activities. 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.

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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, 2008	2007	Increase (Decrease)
(In millions)			
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	99.5	63.4	36.1
Total research and development expenses	$274.9	$202.5	$72.4

For the reasons described above in Results of Operations for the years ended December 31, 2009 and 2008, 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. We shipped $10.7 million of ARCALYST to our U.S. distributors in 2008.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $48.9 million in 2008 from $37.9 million in 2007. In 2008, we incurred $5.2 million of selling expenses related to ARCALYST 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 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 in 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 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, respectively, related to these securities, 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.

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Interest expense of $7.8 million and $12.0 million in 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 taxes and included $0.2 million of interest and penalties. This expense was partially 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.

Revision of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, we became aware that certain of these conditions were applicable to our December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, we are deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

We revised our previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which we are leasing and to adjust our previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability) at each balance sheet date. We also revised our statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of our lease, with a corresponding adjustment to other long-term liabilities.

As previously disclosed in our Quarterly Reports on Form 10-Q for the quarters ended June 30 and September 30, 2009, the above described revisions consisted entirely of non-cash adjustments. They had no impact on our business operations, existing capital resources, or our ability to fund our operating needs, including the preclinical and clinical development of our product candidates. The revisions also had no impact on our previously reported net increases or decreases in cash and cash equivalents in any period and, except for the quarter ended March 31, 2009, had no impact on our previously reported net cash flows from operating activities, investing activities, and financing activities. In addition, these revisions had no impact on our previously reported current assets, current liabilities, and operating revenues. We have not amended previously issued financial statements because, after considering both qualitative and quantitative factors, we determined that the judgment of a reasonable person relying on our previously issued financial statements would not have been changed or influenced by these revisions.

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For comparative purposes, the impact of the above described revisions to our balance sheet as of December 31, 2008 is as follows:

Balance Sheet Impact at December 31, 2008
(In millions)

	December 31, 2008
As originally reported	
Property, plant, and equipment, net	$ 87.9
Total assets	670.0
Other long-term liabilities	5.1
Total liabilities	251.2
Accumulated deficit	(875.9)
Total stockholders' equity	418.8
Total liabilities and stockholders' equity	670.0
As revised	
Property, plant, and equipment, net	$ 142.0
Total assets	724.2
Facility lease obligation	54.2
Other long-term liabilities	2.4
Total liabilities	302.7
Accumulated deficit	(873.3)
Total stockholders' equity	421.5
Total liabilities and stockholders' equity	724.2

For comparative purposes, the impact of the above described revisions to our statements of operations for the period(s) set forth below is as follows:

Statements of Operations Impact for the years ended December 31, 2008 and 2007
(In millions, except per share data)

	December 31,	
	2008	2007
As originally reported		
Research and development expenses	$278.0	$ 201.6
Selling, general, and administrative expenses	49.3	37.9
Total expenses	328.3	239.5
Net loss	(82.7)	(105.6)
Net loss per share, basic and diluted	$ (1.05)	$ (1.59)
As revised		
Research and development expenses	$274.9	$ 202.5
Selling, general, and administrative expenses	48.9	37.9
Total expenses	324.7	240.4
Net loss	(79.1)	(106.5)
Net loss per share, basic and diluted	$ (1.00)	$ (1.61)

These revised amounts are reflected in this Annual Report on Form 10-K for the year ended December 31, 2009.

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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® (rilonacept) product revenue, and investment income.

Sources and Uses of Cash for the Years Ended December 31, 2009, 2008, and 2007

At December 31, 2009, we had $390.0 million in cash, cash equivalents, restricted cash, and marketable securities compared with $527.5 million at December 31, 2008 and $846.3 million at December 31, 2007. 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 2009, 2008, and 2007. In July 2009 and August 2007, we received $20.0 million milestone payments from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO and wet AMD, respectively. In December 2007, we received an $85.0 million upfront payment in connection with our original antibody collaboration agreement 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.

Cash (Used in) Provided by Operations

Net cash used in operations was $72.2 million in 2009 and $89.1 million in 2008, and net cash provided by operations was $27.4 million in 2007. Our net losses of $67.8 million in 2009, $79.1 million in 2008, and $106.5 million in 2007 included $31.3 million, $32.5 million, and $28.1 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of $14.2 million, $11.3 million, and $11.5 million in 2009, 2008, and 2007, respectively.

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 balances 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 $13.0 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 partially 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 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 partially 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 not considered to be substantive for revenue recognition purposes and, therefore, fully deferred, and (iii) the two $20.0 million licensing 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 $19.1 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.

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The majority of our cash expenditures in 2009, 2008, and 2007 were to fund research and development, primarily related to our clinical programs and our preclinical human monoclonal antibody programs. In 2008 and 2007, we made interest payments totaling $9.3 million and $11.0 million, respectively, on our convertible senior subordinated notes. The convertible notes were repaid in full in 2008.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $146 thousand in 2009 and $30.8 million in 2008, and net cash used in investing activities was $85.7 million in 2007. In 2009 and 2008, sales or maturities of marketable securities exceeded purchases by $97.4 million and $65.7 million, respectively, whereas in 2007, purchases of marketable securities exceeded sales or maturities by $67.3 million. Capital expenditures in 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. Capital expenditures in 2007 included the purchase of land and a building in Rensselaer for $9.0 million.

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $31.4 million in 2009 and $319.4 million in 2007, respectively, and net cash used in financing activities was $192.9 million in 2008. In 2009, we received a $23.6 million reimbursement of tenant improvements 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. 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 addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $8.6 million in 2009, $7.9 million in 2008, and $7.6 million in 2007.

Fair Value of Marketable Securities

At December 31, 2009 and 2008, we held marketable securities whose aggregate fair value totaled $181.3 million and $278.0 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	2009		2008	
Investment type	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	$ 80.4	44%	$113.9	41%
U.S. government agency securities	29.6	16%	58.3	21%
U.S. government-guaranteed corporate bonds	48.7	27%	29.8	11%
U.S. government guaranteed collateralized mortgage obligations	3.7	2%	17.4	6%
Corporate bonds	10.3	6%	37.1	13%
Mortgage-backed securities	3.2	2%	10.0	4%
Other asset-backed securities			7.8	3%
Other	5.4	3%	3.7	1%
Total marketable securities	$181.3	100%	$278.0	100%

In addition, at December 31, 2009 and 2008, we had $208.7 million and $249.5 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2009, 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, which we initiated in 2008, reduced the risk profile, as well as the overall yield, of our portfolio during 2009.

In particular, we reduced the proportion of mortgage-backed securities in, and eliminated other asset-backed securities from, the portfolio since they had deteriorated in credit quality and declined in value due to higher delinquency rates on the underlying collateral supporting these securities. The mortgage-backed securities that we

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held at December 31, 2009 are backed by prime and sub-prime residential mortgages and home equity loans. The estimated fair value of our mortgage-backed securities generally ranged from 77% to 99% of par value at December 31, 2009. Our mortgage-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, 2009, we continued to receive monthly payments of principal and interest on our mortgage-backed securities holdings. If the monthly principal and interest payments continue at approximately the current rate, we anticipate that all of the mortgage-backed securities in our portfolio will be repaid within the next two years, and most would be repaid in 2010. However, higher delinquency rates in the underlying collateral supporting mortgage-backed securities in our investment portfolio could result in future impairment charges related to these securities, which could be material.

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.

Changes in Level 3 marketable securities during the year ended December 31, 2009 and 2008 were as follows:

	Level 3 Marketable Securities	
(In millions)	2009	2008
Balance January 1	$ 0.1	$ 7.9
Settlements		(8.2)
Realized gain		1.1
Impairments	(0.1)	(0.7)
Balance December 31		$ 0.1

During the years ended December 31, 2009 and 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 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 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 million in milestone payments upon receipt of specified marketing approvals, including up to

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$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, 2009, we and sanofi-aventis have incurred $598.4 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 $26.6 million, $35.6 million, and $38.3 million, respectively, of our aflibercept development costs in 2009, 2008, and 2007, of which $3.6 million, $6.3 million, and $10.5 million, respectively, were included in accounts receivable as of December 31, 2009, 2008, and 2007. 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 2009, 2008, and 2007, we recognized $9.9 million, $8.8 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. 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 $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. Sanofi-aventis will now 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 are not satisfied. The 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 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 $140.2 million as of December 31, 2009)

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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 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 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 will fund up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $0.5 million were included in accounts receivable at December 31, 2009.

In 2009, 2008, and 2007, sanofi-aventis funded $99.8 million, $72.2 million, and $3.0 million, respectively, of our expenses under the collaboration's discovery agreement and $98.3 million, $25.7 million, and $0.7 million, respectively, of our development costs under the license agreement. Of these amounts, $57.9 million and $25.5 million were included in accounts receivable as of December 31, 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 2009, 2008, and 2007, we recognized $9.9 million, $10.5 million, and $0.9 million of revenue, respectively, related to this up-front payment. In addition, reimbursements by sanofi-aventis of our costs to expand our manufacturing capacity will be 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, as described above.

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 $5.1 million had been received as of December 31, 2009.

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. Prior to December 31, 2017, 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, 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.

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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 Phase 3 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 a Phase 3 study of VEGF Trap-Eye in CRVO. We are eligible to receive up to $70 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 $138.4 million at December 31, 2009) 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 and CRVO 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 2009, 2008, and 2007, we recognized $9.9 million, $12.4 million, and $15.9 million, respectively, of revenue related to these deferred payments. The $20.0 million substantive performance milestone payment received from Bayer HealthCare in July 2009 was recognized as 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 2009, this resulted in a net payment by us of $0.3 million 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. 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. At December 31, 2009 and 2008, accrued expenses included $1.2 million and $9.8 million, respectively, due to 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 $20.0 million annual, non-refundable payments to us in each of 2009, 2008, and 2007. AstraZeneca and Astellas are each required to make up to three additional annual payments of $20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the next annual payment in 2010.

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 2009, 2008, and 2007, we recognized $5.5 million, $4.9 million, and $5.5 million, respectively, of

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revenue related to the NIH Grant, of which $1.2 million and $1.3 million, respectively, was receivable at the end of 2009 and 2008. In 2010, we expect to receive funding of approximately $5.5 million for reimbursement of Regeneron 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 with respect to our *VelocImmune* license agreements with AstraZeneca and Astellas or our antibody collaboration with sanofi-aventis. In addition, 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 (as amended in November 2009). In 2009 and 2008, we recognized $2.3 million and $2.7 million, respectively, of expense related to the Cellectis 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).

Lease – Tarrytown, New York Facilities:

We lease approximately 537,100 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 130,900 square feet of additional new space that is under construction in a third new building (Building C), which is expected to be completed in mid-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 290,400 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 the newly constructed space 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 (as described above under "Revision of Previously Issued Financial Statements"), 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, 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.

In connection with Buildings A and B, we capitalized our landlord's costs of constructing these new facilities, which totaled $58.2 million as of December 31, 2009, and recognized a corresponding facility lease obligation of $58.2 million. We also recognized, as an additional facility lease obligation, reimbursements totaling $23.6 million from our landlord during 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, 2009 and 2008, the facility lease obligation balance in connection with these new facilities was $81.0 million and $54.2 million, respectively.

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In addition, as described above, we amended our lease in December 2009 to include additional new laboratory and office space in Building C that is under construction. As of December 31, 2009, we capitalized $27.8 million of our landlord's costs of constructing these new facilities, and recognized a corresponding facility lease obligation of $27.8 million. Monthly lease payments on these facilities will commence 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 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, 2009, the facility lease obligation balance in connection with these additional new facilities was $28.0 million.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $97.3 million in 2009, $34.9 million in 2008, and $18.4 million in 2007. As described above, $23.6 million of tenant improvement costs we incurred in Tarrytown were reimbursed by our landlord in 2009. We expect to incur capital expenditures of approximately $80 to $110 million in 2010 and approximately $40 to $60 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our newly leased Tarrytown facilities in Building C. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. We also expect to be reimbursed for a portion of the capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements

Our total expenses for research and development from inception through December 31, 2009 have been approximately $2.0 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 a collaborator's development expenses, where applicable, of $333.7 million, $230.6 million, and $108.2 million in 2009, 2008, and 2007, 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 our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the preclinical and clinical development of product candidates, including rilonacept, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and early preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our amended and expanded antibody collaboration with sanofi-aventis.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2009. 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]	$ 96.2	$ 6.3	$11.6	$12.4	$ 65.9
Purchase obligations[2]	150.6	112.5	38.1		
Other long-term liabilities[3]	205.4	8.2	22.4	26.6	148.2
Total contractual obligations	$452.2	$127.0	$72.1	$39.0	$214.1

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(1) Excludes future contingent costs for utilities, real estate taxes, and operating expenses included in our rent. In 2009, these costs were $8.4 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.

As described above, in February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. As a result, total contractual obligations, as detailed in the table above, will increase (i) from 127.0 million to $130.9 million for the year ending December 31, 2010, (ii) from $72.1 million to $80.0 million for the two-year period beginning January 1, 2011, (iii) from $39.0 million to $47.0 million for the two-year period beginning January 1, 2013, and (iv) from $214.1 million to $251.6 million for the fiscal years beginning January 1, 2015 and thereafter.

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 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 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 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. For example, if we choose to commercialize products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that

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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 would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than our operating leases and a $1.6 million letter of credit issued to our landlord 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, 2009, 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 October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate arrangement consideration in a multiple-element revenue arrangement by requiring the use of estimated selling prices to allocate arrangement 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 are required to adopt this amended guidance effective for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. We are currently evaluating the impact that this guidance will have 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 investment of excess cash 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 and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, 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 estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $0.6 million and $1.9 million decrease in the fair value of our investment portfolio at December 31, 2009 and 2008, respectively.

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, $2.5 million, and $5.9 million in 2009, 2008, and 2007, respectively.

The current economic environment and the deterioration in the credit quality of issuers of securities that we hold increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included on pages F-1 through F-35 of this report. The supplementary financial information required by this Item is included at page F-35 of this report.

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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, 2009. The effectiveness of our internal control over financial reporting as of December 31, 2009 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, 2009 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.

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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 2010 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 2010 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 2010 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 2010 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 2010 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.

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3. *Exhibits*

Exhibit Number			Description
3.1	(o)	-	Restated Certificate of Incorporation.
3.2	(a)	-	By-Laws, as amended.
10.1 +	(b)	-	1990 Amended and Restated Long-Term Incentive Plan.
10.2 +	(p)	-	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.
10.2.4 +	(d)	-	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.
10.2.5 +	(t)	-	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.
10.2.6 +	(t)	-	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.
10.3 +	(s)	-	Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D.
10.4* +	(e)	-	Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D.
10.5 +	(s)	-	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 Registrant, Immunex Corporation, and Amgen Inc.
10.7*	(u)	-	IL-1 Antibody Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.
10.8*	(u)	-	Trap-2 Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.
10.9*	(g)	-	Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.9.1*	(e)	-	Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 31, 2004.
10.9.2	(h)	-	Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of January 7, 2005.
10.9.3*	(i)	-	Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 21, 2005.
10.9.4*	(i)	-	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.
10.10*	(j)	-	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and the Registrant.
10.11*	(k)	-	Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007, by and between AstraZeneca UK Limited and the Registrant.
10.12	(l)	-	Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and the Registrant.
10.12.1*	(n)	-	First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of October 24, 2007.

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10.12.2	(r)	-	Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of September 30, 2008.
10.12.3	(t)	-	Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 29, 2009.
10.12.4	(v)	-	Fourth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of December 3, 2009.
10.12.5	(w)	-	Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010.
10.13*	(m)	-	Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and the Registrant.
10.14*		-	Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.15*		-	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.
10.16	(o)	-	Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique Du Nord, sanofi-aventis US LLC, and the Registrant.
10.17	(o)	-	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.
10.17.1		-	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.
10.18*	(q)	-	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.

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 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 September 30, 2003, filed November 12, 2003.

(h) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.

(i) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2005, filed February 28, 2006.

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(j) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.

(k) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2006, filed March 12, 2007.

(l) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.

(m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2007, filed May 4, 2007.

(n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2007, filed November 7, 2007.

(o) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2007, filed February 27, 2008.

(p) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed June 17, 2008.

(q) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2008, filed August 1, 2008.

(r) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2008, filed November 5, 2008.

(s) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2008, filed February 26, 2009.

(t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2009, filed April 30, 2009.

(u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2009, filed August 4, 2009.

(v) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 8, 2009.

(w) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed February 16, 2010.

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* 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.

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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 18, 2010

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/ ARTHUR F. RYAN Arthur F. Ryan	*Director*
/s/ ERIC M. SHOOTER Eric M. Shooter, Ph.D.	*Director*
/s/ GEORGE L. SING George L. Sing	*Director*

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REGENERON PHARMACEUTICALS, INC.

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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, 2009 and December 31, 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 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, 2009, 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.

PricewaterhouseCoopers LLP

New York, New York
February 18, 2010

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REGENERON PHARMACEUTICALS, INC.
BALANCE SHEETS

December 31, 2009 and 2008
(In thousands, except share data)

	2009	2008 *(Revised - see Note 11)*
ASSETS		
Current assets		
Cash and cash equivalents	$ 207,075	$ 247,796
Marketable securities	134,255	226,954
Accounts receivable from the sanofi-aventis Group	62,703	33,302
Accounts receivable - other	2,865	1,910
Prepaid expenses and other current assets	18,610	11,480
Total current assets	425,508	521,442
Restricted cash	1,600	1,650
Marketable securities	47,080	51,061
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	259,676	142,035
Other assets	7,338	8,032
Total assets	$ 741,202	$ 724,220
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 49,031	$ 36,168
Deferred revenue from sanofi-aventis, current portion	17,523	21,390
Deferred revenue - other, current portion	27,021	26,114
Total current liabilities	93,575	83,672
Deferred revenue from sanofi-aventis	90,933	105,586
Deferred revenue - other	46,951	56,835
Facility lease obligations	109,022	54,182
Other long term liabilities	3,959	2,431
Total liabilities	344,440	302,706
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 - 2,244,698 in 2009 and 2,248,698 in 2008	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 78,860,862 in 2009 and 77,642,203 in 2008	79	78
Additional paid-in capital	1,336,732	1,294,813
Accumulated deficit	(941,095)	(873,265)
Accumulated other comprehensive income (loss)	1,044	(114)
Total stockholders' equity	396,762	421,514
Total liabilities and stockholders' equity	$ 741,202	$ 724,220

The accompanying notes are an integral part of the financial statements.

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REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2009, 2008, and 2007
(In thousands except share data)

	2009	2008 *(Revised - see Note 11)*	2007 *(Revised - see Note 11)*
Revenues			
Sanofi-aventis collaboration revenue	$247,140	$153,972	$ 51,687
Other collaboration revenue	67,317	31,166	35,961
Technology licensing	40,013	40,000	28,421
Net product sales	18,364	6,249	
Contract research and other	6,434	7,070	8,955
	379,268	238,457	125,024
Expenses			
Research and development	398,762	274,903	202,468
Selling, general, and admistrative	52,923	48,880	37,929
Cost of goods sold	1,686	923	
	453,371	324,706	240,397
Loss from operations	(74,103)	(86,249)	(115,373)
Other income (expense)			
Investment income	4,488	18,161	20,897
Interest expense	(2,337)	(7,752)	(12,043)
Loss on early extinguishment of debt		(938)	
	2,151	9,471	8,854
Net loss before income tax expense	(71,952)	(76,778)	(106,519)
Income tax (benefit) expense	(4,122)	2,351	
Net loss	$ (67,830)	$ (79,129)	$(106,519)
Net loss per share, basic and diluted	$ (0.85)	$ (1.00)	$ (1.61)
Weighted average shares outstanding, basic and diluted	79,782	78,827	66,334

The accompanying notes are an integral part of the financial statements.

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REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2009, 2008, and 2007
(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, 2006	2,270	$ 2	63,131	$63	$ 904,407	$(687,617)	$ (231)	$ 216,624	
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						(106,519)		(106,519)	$(106,519)
Change in net unrealized gain (loss) on marketable securities							401	401	401
Balance, December 31, 2007 ***(Revised- see Note 11)***	2,260	2	76,592	77	1,253,235	(794,136)	170	459,348	$(106,118)
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					32,523			32,523	
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 ***(Revised - see Note 11)***	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)

The accompanying notes are an integral part of the financial statements.

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REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2009, 2008, and 2007

	2009	2008	2007
		(In thousands)	
Cash flows from operating activities			
Net loss	$ (67,830)	$ (79,129)	$(106,519)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities			
Depreciation and amortization	14,247	11,287	11,487
Non-cash compensation expense	31,259	32,523	28,075
Other non-cash expenses	(382)		
Loss on early extinguishment of debt		938	
Net realized (gain) loss on marketable securities	(56)	1,310	5,943
Changes in assets and liabilities			
Increase in accounts receivable	(30,356)	(16,892)	(10,827)
Increase in prepaid expenses and other assets	(4,574)	(6,560)	(9,649)
(Decrease) increase in deferred revenue	(27,497)	(26,834)	89,764
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	12,959	(5,729)	19,098
Total adjustments	(4,400)	(9,957)	133,891
Net cash (used in) provided by operating activities	(72,230)	(89,086)	27,372
Cash flows from investing activities			
Purchases of marketable securities	(199,997)	(581,139)	(594,446)
Sales or maturities of marketable securities	297,411	646,861	527,169
Capital expenditures	(97,318)	(34,857)	(18,446)
Decrease (increase) in restricted cash	50	(50)	
Net cash provided by (used in) investing activities	146	30,815	(85,723)
Cash flows from financing activities			
Repurchases or repayment of notes payable		(200,807)	
Proceeds in connection with facility lease obligation	23,640		
Payments in connection with facility lease obligation	(875)		
Net proceeds from the issuance of Common Stock	8,598	7,949	319,400
Net cash provided by (used in) financing activities	31,363	(192,858)	319,400
Net (decrease) increase in cash and cash equivalents	(40,721)	(251,129)	261,049
Cash and cash equivalents at beginning of period	247,796	498,925	237,876
Cash and cash equivalents at end of period	$ 207,075	$ 247,796	$ 498,925
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 2,525	$ 9,348	$ 11,000
Cash paid for income taxes		$ 3,079	

The accompanying notes are an integral part of the financial statements.

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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 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, and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed 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.

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.

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	7-35 years
Laboratory and other equipment	3-10 years
Furniture and fixtures	5 years

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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 has obtained, applied for, or is applying for, a number of 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 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

Certain reclassifications have been made to our prior year revenue amounts to conform to the 2009 presentation.

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

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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 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. For example, during the fourth quarter of 2008, the Company extended its estimated performance period in connection with the up-front and non-substantive 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 collaboration 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. In addition, in connection with 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 up-front payment previously received from sanofi-aventis pursuant to the companies' antibody collaboration. The effect of this change in estimate resulted in the recognition of $0.6 million less in collaboration revenue in the fourth quarter of 2009, compared to amounts recognized in each of the prior three quarters of 2009. 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 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.

c. Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST® (rilonacept) for the treatment of CAPS. 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. 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

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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 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.

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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 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. 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.

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 the Company adopted on January 1, 2007. Such guidance 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. For the years ended December 31, 2009, 2008, and 2007, the Company has not recognized any income tax positions that were deemed uncertain under the recognition thresholds and measurement attributes prescribed by FASB authoritative guidance.

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, 2009, 2008, and 2007 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.

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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, 2009, 2008, and 2007 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. Collaboration revenue in 2009 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:

- 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.
- 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.

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- 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 we consider the options' performance conditions 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.
- The extent to which deferred tax assets and liabilities are offset by a valuation allowance.

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 arrangement consideration in a multiple-element revenue arrangement by requiring the use of estimated selling prices to allocate arrangement 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 be required to adopt this amended guidance effective for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management is currently evaluating the impact that this guidance will have 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 $320.9 million, $192.2 million, and $96.6 million in 2009, 2008, and 2007, 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 $333.7 million, $230.6 million, and $108.2 million in 2009, 2008, and 2007, respectively. Significant agreements of this kind are described below.

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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 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 $598.4 million as of December 31, 2009, 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. The Company recognized $36.5 million, $44.4 million, and $47.1 million of collaboration development revenue in 2009, 2008, and 2007, respectively, in connection with the Aflibercept Agreement, as amended. At December 31, 2009 and 2008, amounts receivable from sanofi-aventis totaled $3.6 million and $6.3 million, respectively, and deferred revenue was $42.5 million and $52.4 million, respectively, in connection with the Aflibercept Agreement.

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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 funded $174.5 million of the Company's research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against those targets 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 will 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 are not satisfied. 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 will retain 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 five 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 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 $140.2 million as of December 31, 2009) 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 will fund 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.

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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 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 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.

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 Antibody Collaboration, the Company recognized $210.7 million, $109.6 million, and $4.6 million of collaboration revenue in 2009, 2008, and 2007, respectively. In addition, at December 31, 2009 and 2008, amounts receivable from sanofi-aventis totaled $59.1 million and $27.0 million and deferred revenue was $66.0 million and $74.6 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 addition, the Company is eligible to receive up to $70 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. The Company is also eligible to receive up to $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 $138.4 million as of December 31, 2009) 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.

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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 diabetic macular edema ("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 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. 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. 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.

The Company recognized $67.3 million, $31.2 million, and $35.9 million of collaboration revenue from Bayer HealthCare in 2009, 2008, and 2007, respectively. In 2009, collaboration revenue from Bayer HealthCare included the $20.0 million milestone payment received in July 2009 which, for the purpose of revenue recognition, was considered substantive. In addition, in 2009, 2008, and 2007, the Company recognized as additional research and development expense $37.7 million, $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 expenses under the collaboration, $1.2 million and $9.8 million was payable to Bayer HealthCare at December 31, 2009 and 2008, respectively. In addition, at December 31, 2009 and 2008, deferred revenue from the Company's collaboration with Bayer HealthCare was $56.8 million and $66.7 million, respectively.

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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 2009, 2008, and 2007, the Company recognized contract research revenue of $5.5 million, $4.9 million, and $5.5 million, respectively, from the NIH Grant.

4. 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 annual, non-refundable payment to the Company in each of 2009, 2008, and 2007. Each annual payment is deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. AstraZeneca is required to make up to three additional annual payments of $20.0 million, subject to their ability to terminate the agreement after making the next annual payment in 2010. 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, 2009, 2008, and 2007, the Company recognized $20.0 million, $20.0 million, and $17.1 million of technology licensing revenue. In addition, deferred revenue at December 31, 2009, 2008, and 2007 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 annual, non-refundable payment to the Company in each of 2009, 2008, and 2007. Each annual payment is deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. Astellas is required to make up to three additional annual payments of $20.0 million, subject to their ability to terminate the agreement after making the next annual payment in 2010. 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, 2009, 2008, and 2007, the Company recognized $20.0 million, $20.0 million, and $11.3 million of technology licensing revenue. In addition, deferred revenue at December 31, 2009, 2008, and 2007 was $8.7 million.

5. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. For the years-ended December 31, 2009 and 2008, the Company recognized as revenue $18.4 million and $6.3 million, respectively, of ARCALYST net product sales for which the right of return no longer existed and rebates could be reasonably estimated. At December 31, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled $4.8 million and $4.0 million, respectively.

Cost of goods sold related to ARCALYST sales totaled $1.7 million and $0.9 million for the years ended December 31, 2009 and 2008, respectively, and consisted primarily of royalties (see Note 11b). To date, ARCALYST shipments to the Company's customers have 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, 2009, the Company had $0.4 million of inventoried work-in-process costs related to ARCALYST, which is included in prepaid expenses and other current assets. There were no capitalized inventory costs at December 31, 2008.

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6. Marketable Securities

Marketable securities at December 31, 2009 and 2008 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was $5.5 million and $3.7 million at December 31, 2009 and 2008, respectively, and the aggregate cost basis of which was $4.0 million and $4.1 million at December 31, 2009 and 2008, respectively. 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, 2009 and 2008. The Company classifies its debt securities, other than mortgage-backed and other asset-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed and other asset-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair	Unrealized Holding		
At December 31, 2009	**Cost Basis**	**Value**	**Gains**	**(Losses)**	**Net**
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
Mortgage-backed securities	2,471	2,338		$ (133)	(133)
U.S. government guaranteed collateralized mortgage obligations	3,612	3,662	50		50
	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
At December 31, 2008					
Maturities within one year					
U.S. government obligations	$170,993	$172,253	$1,260		$1,260
Corporate bonds	26,894	26,662	25	$ (257)	(232)
Mortgage-backed securities	9,098	8,420		(678)	(678)
Other asset-backed securities	7,842	7,829		(13)	(13)
U.S. government guaranteed collateralized mortgage obligations	11,742	11,792	50		50
	226,569	226,956	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)
Mortgage-backed securities	1,821	1,556		(265)	(265)
U.S. government guaranteed collateralized mortgage obligations	5,297	5,570	273		273
	47,417	47,351	432	(498)	(66)
	$273,986	$274,307	$1,767	$(1,446)	$ 321

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At December 31, 2009 and 2008, marketable securities included an additional unrealized gain of $1.4 million and an additional unrealized loss of $0.4 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, 2009 and 2008. The debt securities listed at December 31, 2009 mature at various dates through December 2011.

	Less than 12 Months		12 Months or Greater		Total	
At December 31, 2009	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
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)
At December 31, 2008						
Corporate bonds	$15,559	$(287)	$ 2,933	$ (79)	$18,492	$ (366)
Government guaranteed corporate bonds	11,300	(124)			11,300	(124)
Mortgage-backed securities	871	(74)	9,104	(869)	9,975	(943)
Other asset-backed securities	7,829	(13)			7,829	(13)
Equity securities	3,608	(436)			3,608	(436)
	$39,167	$(934)	$12,037	$(948)	$51,204	$(1,882)

Realized gains and losses are included as a component of investment income. 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. For the year ended December 31, 2007, 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.

The Company's assets that are measured at fair value on a recurring basis, at December 31, 2009 and 2008, were as follows:

		Fair Value Measurements at Reporting Date Using		
Description	**Fair Value at December 31, 2009**	**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				
U.S. government obligations	$109,940		$109,940	
U.S. government guaranteed corporate bonds	48,684		48,684	
Corporate bonds	10,342		10,342	
Mortgage-backed securities	3,238		3,238	
U.S. government guaranteed collateralized mortgage obligations	3,662		3,662	
Equity securities	5,469	5,469		
Total	$181,335	$5,469	$175,866	

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		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				
U.S. government obligations	$172,253		$172,253	
U.S. government guaranteed corporate bonds	29,811		29,811	
Corporate bonds	37,076		37,076	
Mortgage-backed securities	9,976		9,976	
Other asset backed securities	7,829		7,829	
U.S. government guaranteed collateralized mortgage obligations	17,362		17,362	
Equity securities	3,708	$3,608		$100
Total	$278,015	$3,608	$274,307	$100

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 the years ended December 31, 2009 and 2007, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities. 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 $2.0 million carrying 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 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 years ended December 31, 2009 and 2008, the Company recognized an additional $0.1 million and $0.7 million, respectively, in other-than-temporary impairment charges related to one of these marketable securities.

There were no unrealized gains or losses related to the Company's Level 3 marketable securities for the years ended December 31, 2009 and 2008. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities, and no transfers of marketable securities between the Level 2 and Level 3 classifications, during the years ended December 31, 2009 and 2008.

Changes in marketable securities included in Level 3 during the years ended December 31, 2009 and 2008 were as follows:

	Level 3 Marketable Securities	
	2009	2008
Balance, January 1	$ 100	$ 7,950
Settlements		(8,194)
Realized gain		1,044
Impairments	(100)	(700)
Balance, December 31	$	$ 100

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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.

The current economic environment and the deterioration in the credit quality of issuers of securities that the Company holds increase the risk of potential declines in the current market value of marketable securities in the Company's investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

7. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2009 and 2008 consist of the following:

	2009	2008
Land	$ 2,117	$ 2,117
Building and improvements	177,710	74,343
Leasehold improvements	4,023	2,720
Construction-in-progress	58,541	78,702
Laboratory and other equipment	114,099	75,935
Furniture, computer and office equipment, and other	15,964	7,501
	372,454	241,318
Less, accumulated depreciation and amortization	(112,778)	(99,283)
	$ 259,676	$ 142,035

Building and improvements at December 31, 2009 includes $58.2 million 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 December 31, 2009 and 2008 includes $27.8 million and $54.2 million, respectively, of costs incurred by the Company's landlord in connection with these new facilities. See Note 11a.

The Company capitalized interest costs of $0.5 million in 2009. The Company did not capitalize any interest costs in 2008 or 2007.

Depreciation and amortization expense on property, plant, and equipment amounted to $14.2 million, $10.6 million, and $10.4 million for the years ended December 31, 2009, 2008, and 2007, respectively.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2009 and 2008 consist of the following:

	2009	2008
Accounts payable	$18,638	$ 6,268
Payable to Bayer HealthCare	1,186	9,799
Accrued payroll and related costs	9,444	5,948
Accrued clinical trial expense	11,673	4,273
Accrued property, plant, and equipment expenses	1,883	5,994
Accrued expenses, other	6,207	3,886
	$49,031	$36,168

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9. Deferred Revenue

Deferred revenue as of December 31, 2009 and 2008 consists of the following:

	2009	2008
Current portion:		
Received from sanofi-aventis (see Note 3a)	$ 17,523	$ 21,390
Received from Bayer HealthCare (see Note 3b)	9,884	9,884
Received for technology license agreements (see Note 4)	11,579	11,579
Other	5,558	4,651
	$ 44,544	$ 47,504
Long-term portion:		
Received from sanofi-aventis (see Note 3a)	$ 90,933	$105,586
Received from Bayer HealthCare (see Note 3b)	46,951	56,835
	$137,884	$162,421

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 the Tarrytown Lease, additional new space that is under construction in a third new building ("Building C"), which is expected to be completed in mid-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, as well as 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 the newly constructed space 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.

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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 is collateralized by a $1.6 million bank certificate of deposit. The certificate of deposit has been classified as restricted cash at December 31, 2009 and 2008.

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 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 also leases certain laboratory and office equipment under operating leases which expire at various times through 2011.

Revisions of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, the Company became aware that certain of these conditions were applicable to its Tarrytown Lease of new laboratory and office facilities in Buildings A and B. As a result, the Company is deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were 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 addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

The Company revised its previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which the Company is leasing and to adjust the Company's previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability) at each balance sheet date. The Company also revised its statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of its lease, with a corresponding adjustment to other long-term liabilities.

As previously disclosed in the Company's Quarterly Reports on Form 10-Q for the quarters ended June 30 and September 30, 2009, the above described revisions consisted entirely of non-cash adjustments. They had no impact on the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs, including the preclinical and clinical development of its product candidates. The revisions also had no impact on the Company's previously reported net increases or decreases in cash and cash equivalents in any period and, except for the quarter ended March 31, 2009, had no impact on the Company's previously reported net cash flows from operating activities, investing activities, and financing activities. In addition, these revisions had no impact on the Company's previously reported current assets, current liabilities, and operating revenues. We have not amended previously issued financial statements because, after considering both qualitative and quantitative factors, the Company determined that the judgment of a reasonable person relying on the Company's previously issued financial statements would not have been changed or influenced by these revisions.

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For comparative purposes, the impact of the above described revisions to the Company's balance sheet as of December 31, 2008 is as follows:

Balance Sheet Impact at December 31, 2008
(in millions)

	December 31, 2008
As originally reported	
Property, plant, and equipment, net	$ 87.9
Total assets	670.0
Other long-term liabilities	5.1
Total liabilities	251.2
Accumulated deficit	(875.9)
Total stockholders' equity	418.8
Total liabilities and stockholders' equity	670.0
As revised	
Property, plant, and equipment, net	$ 142.0
Total assets	724.2
Facility lease obligation	54.2
Other long-term liabilities	2.4
Total liabilities	302.7
Accumulated deficit	(873.3)
Total stockholders' equity	421.5
Total liabilities and stockholders' equity	724.2

For comparative purposes, the impact of the above described revisions to the Company's statements of operations for the period(s) set forth below is as follows:

Statements of Operations Impact for the years ended December 31, 2008 and 2007
(in millions, except per share data)

	December 31,	
	2008	2007
As originally reported		
Research and development expenses	$278.0	$ 201.6
Selling, general, and administrative expenses	49.3	37.9
Total expenses	328.3	239.5
Net loss	(82.7)	(105.6)
Net loss per share, basic and diluted	$ (1.05)	$ (1.59)
As revised		
Research and development expenses	$274.9	$ 202.5
Selling, general, and administrative expenses	48.9	37.9
Total expenses	324.7	240.4
Net loss	(79.1)	(106.5)
Net loss per share, basic and diluted	$ (1.00)	$ (1.61)

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These revised amounts are reflected in the Company's financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2009.

Commitments under Operating Leases

The estimated future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2010	$ 5,919	$387	$ 6,306
2011	6,336	160	6,496
2012	5,020	48	5,068
2013	6,159	2	6,161
2014	6,262		6,262
Thereafter	65,883		65,883
	$95,579	$597	$96,176

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
2009	$7,722	$395	$8,117
2008	6,530	416	6,946
2007	5,551	363	5,914

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, $8.4 million, and $8.8 million for the years ended December 31, 2009, 2008, and 2007, respectively.

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 $58.2 million as of December 31, 2009, and recognized a corresponding facility lease obligation of $58.2 million. The Company also recognized, as additional facility lease obligation, reimbursements totaling $23.6 million from the Company's landlord during 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 year ended December 31, 2009, the Company recognized in its statement of operations $2.3 million of interest expense in connection with the facility lease obligation. At December 31, 2009 and 2008, the facility lease obligation balance in connection with these new facilities was $81.0 million and $54.2 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 these new facilities 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, 2009, the Company capitalized $27.8 million of the landlord's costs of constructing the new facilities, and recognized a corresponding facility lease obligation of $27.8 million. 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,

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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, 2009, the facility lease obligation balance in connection with these additional new facilities was $28.0 million.

The estimated future minimum noncancelable commitments under these facility lease obligations, as of December 31, 2009, were as follows:

December 31,	Buildings A and B	Building C	Total
2010	$ 8,152		$ 8,152
2011	8,381	$ 2,675	11,056
2012	8,616	2,753	11,369
2013	8,856	4,270	13,126
2014	9,103	4,389	13,492
Thereafter	99,981	48,172	148,153
	$143,089	$62,259	$205,348

In February 2010, the Company received $47.5 million from the Company's landlord in connection with tenant improvement costs for Buildings A, B, and C. As a result, future minimum noncancellable commitments under facility lease obligations, as detailed in the table above, will increase by $3.9 million in each of the five years from 2010 to 2014 and $37.5 million for the years thereafter.

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 $2.8 million, $3.5 million, and $1.0 million for the years ended December 31, 2009, 2008, and 2007, respectively.

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 years ended December 31, 2009 and 2008, ARCALYST royalties totaled $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 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 on any revenue from commercial sales of antibodies from the Company's *VelocImmune* technology.

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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 2009 and 2008, the Company recognized $2.3 million and $2.7 million, respectively, of expense in connection with the Cellectis Payment. At December 31, 2009 and 2008, the unamortized balance of the Cellectis Payment, which was included in other assets, was $7.6 million and $9.8 million, respectively. The Company estimates that it will recognize expense of $1.1 million in 2010, $1.0 million in 2011, and $0.9 million in each of 2012, 2013, and 2014, in connection with the Cellectis Payment.

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 (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 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 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.

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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 28,816,184 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.

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, 2009, there were 3,949,767 shares available for future grants under the 2000 Incentive Plan.

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a. Stock Options

Transactions involving stock option awards during 2009 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, 2008	20,133,910	$17.53		
2009: Granted	3,490,560	$20.69		
Forfeited	(390,328)	$19.17		
Expired	(74,589)	$21.46		
Exercised	(1,370,798)	$10.19		
Outstanding at December 31, 2009	21,788,755	$18.45	6.45	$150,472
Vested and expected to vest at December 31, 2009	21,263,460	$18.44	6.39	$147,516
Exercisable at December 31, 2009	12,504,511	$18.18	4.98	$ 96,967

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 2009, 2008, and 2007 was $13.2 million, $11.9 million, and $12.6 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 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, 2007, 2008, and 2009. The fair value of each option granted under the 2000 Incentive Plan during 2009, 2008, and 2007 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
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
2009:			
Exercise price equal to Market Price	3,490,560	$20.69	$10.89

For the years ended December 31, 2009, 2008, and 2007, $27.4 million, $30.3 million, and $28.0 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, 2009, there was $44.8 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 1.9 years.

In addition, there were 1,939,760 performance-based options which were unvested as of December 31, 2009 of which, subject to the optionee satisfying certain service conditions, 664,760 options that were issued in 2007 would vest upon achieving certain defined sales targets for the Company's products and 1,275,000 options that were issued in 2008 and 2009 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, 2009, the Company estimates that approximately 850,000 of the performance-based options tied to achieving development milestones will vest since

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the Company considers these options' performance conditions to be probable of attainment. As a result, in 2009, the Company recognized $1.7 million of non-cash stock-based compensation expense related to these performance options. As of December 31, 2009, there was $8.7 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 2.5 years. In addition, potential compensation cost of $7.7 million related to those performance options 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 2009, 2008, and 2007.

	2009	2008	2007
Expected volatility	54%	53%	53%
Expected lives from grant date	5.9 years	5.5 years	5.6 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	2.87%	1.73%	3.60%

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, 2009 is summarized below:

Restricted Stock:	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2008	500,000	$21.92
Outstanding at December 31, 2009	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 lapses, 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.

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. The Company recognized non-cash stock-based employee compensation expense from Restricted Stock awards of $2.2 million, $2.2 million, and $0.1 million in 2009, 2008, and 2007, respectively. As of December 31, 2009, there were 500,000 unvested shares

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of Restricted Stock outstanding and $6.5 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 3 years.

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, 2009, 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 recorded Contribution expense of $2.6 million in 2009, $1.5 million in 2008, and $1.4 million in 2007, and such amounts were accrued as liabilities at December 31, 2009, 2008, and 2007, respectively. 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 Savings Plan in satisfaction of these obligations.

16. Income Taxes

For the year ended December 31, 2009, the Company incurred a net loss for tax purposes and recognized a full tax valuation 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 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 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.

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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.

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2009 and 2008 is as follows:

	2009	2008
Deferred tax assets:		
Net operating loss carry-forward	$ 200,266	$ 161,790
Fixed assets	13,833	18,612
Deferred revenue	73,865	85,251
Deferred compensation	29,736	22,942
Research and experimental tax credit carry-forward	22,377	22,295
Capitalized research and development costs	49,107	59,661
Other	10,142	9,825
Valuation allowance	(399,326)	(380,376)

The Company's valuation allowance increased by $19.0 million in 2009, due primarily to the increase in the net operating loss carry-forward. In 2008, the Company's valuation allowance increased by $37.4 million, 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.

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. As described in Note 2 under "Income Taxes", the implementation of FASB authoritative guidance on January 1, 2007, and for the years ended December 31, 2009, 2008, and 2007, 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 prescribed recognition thresholds and measurement attributes.

As of December 31, 2009 and 2008, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2009, the Company had available for tax purposes unused net operating loss carry-forwards of $516.3 million which will expire in various years from 2018 to 2029 and included $21.7 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 2010 to 2029. 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.

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.

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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 2009, 2008, and 2007, 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,		
	2009	2008	2007
Net loss (Numerator)	$(67,830)	$(79,129)	$(106,519)
Weighted-average shares, in thousands (Denominator)	79,782	78,827	66,334
Basic and diluted net loss per share	$ (0.85)	$ (1.00)	$ (1.61)

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,		
	2009	2008	2007
Options:			
Weighted average number, in thousands	20,040	17,598	15,385
Weighted average exercise price	$ 17.66	$ 17.31	$ 15.97
Restricted Stock:			
Weighted average number, in thousands	500	500	21
Convertible Debt:			
Weighted average number, in thousands			6,611
Conversion price			$ 30.25

19. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at December 31, 2009, 2008, and 2007 were $9.8 million, $7.0 million, and $1.7 million of accrued capital expenditures, respectively.

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 $31.7 million and $32.6 million during 2009 and 2008, 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 accounts payable and accrued expenses at December 31, 2008, 2007, and 2006 were $1.5 million, $1.1 million, and $1.4 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2009, 2008, and 2007, the Company contributed 81,086, 58,575, and 64,532, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in other assets at December 31, 2009 was $0.7 million due to the Company in connection with employee exercises of stock options in December 2009.

Included in marketable securities at December 31, 2009, 2008, and 2007 were $0.6 million, $1.7 million, and $2.2 million of accrued interest income, respectively.

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20. Subsequent Events

The Company has evaluated subsequent events through February 18, 2010, the date on which the financial statements were issued, and has determined that there are no subsequent events that require adjustments to the financial statements for the year ended December 31, 2009. As described in Note 11a under "Facility Lease Obligations," in February 2010, the Company received $47.5 million from the Company's landlord in Tarrytown, New York, in connection with tenant improvement costs.

21. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2009 and 2008 are set forth in the following tables.

	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)

	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	(11,847)	(18,689)	(19,084)	(29,509)
Net loss per share, basic and diluted:	$ (0.15)	$ (0.24)	$ (0.24)	$ (0.37)

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Samsung Bioepis Exhibit 1017, pg. 5443

Corporate information

Common stock and related matters

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.

2008	HIGH	LOW
First Quarter	$ 25.25	$ 15.61
Second Quarter	21.68	13.75
Third Quarter	24.00	13.29
Fourth Quarter	22.82	12.62
2009	**HIGH**	**LOW**
First Quarter	$ 20.08	$ 11.81
Second Quarter	18.42	12.11
Third Quarter	23.49	16.05
Fourth Quarter	24.97	15.02

As of April 14, 2010, there were 459 shareholders of record of our Common Stock and 39 shareholders of record of our Class A Stock. The closing bid price for the Common Stock on that date was $26.39.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

Corporate office

777 Old Saw Mill River Road
Tarrytown, NY 10591-6707
(914) 345-7400

Annual meeting

The 2010 Annual Meeting of Shareholders will be held on Friday, June 11, 2010 at 10:30 a.m. at the Westchester Marriott Hotel, 670 White Plains Road, Tarrytown, NY 10591.

Shareholders' inquiries

Inquiries relating to stock transfer or lost certificates and notices of changes of address should be directed to our Transfer Agent, American Stock Transfer & Trust Co., 59 Maiden Lane, Plaza Level, New York, NY 10038, (800) 937-5449. General information regarding the Company, recent press releases, and SEC filings are available on our web site at www regeneron.com, or can be obtained by contacting our Investor Relations Department at (914) 345-7741.

Transfer agent and registrar

American Stock Transfer & Trust Co.
59 Maiden Lane
Plaza Level
New York, NY 10038

Independent registered public accounting firm

PricewaterhouseCoopers LLP

REGENERON® and the following are registered trademarks of Regeneron Pharmaceuticals, Inc.: ARCALYST®, VelocImmune®, and VelociGene®. Lucentis® is a registered trademark of Genentech, Inc.

Forward-looking statements and risk factors

This Annual Report discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2009. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

Corporate directory

Directors

P. Roy Vagelos, M.D.
Chairman of the Board
Retired Chairman of the Board
and Chief Executive Officer,
Merck & Co., Inc.

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Charles A. Baker
Retired Chairman of the Board,
President and Chief Executive Officer,
The Liposome Company, Inc.

Michael S. Brown, M.D.
Regental Professor and Director,
Jonsson Center for Molecular Genetics
The University of Texas
Southwestern Medical Center at Dallas

Alfred G. Gilman, M.D., Ph.D.
Chief Scientific Officer,
Cancer Prevention and
Research Institute of Texas and
Regental Professor of Pharmacology,
Emeritus
The University of Texas
Southwestern Medical Center at Dallas

Joseph L. Goldstein, M.D.
Regental Professor and Chairman,
Department of Molecular Genetics
The University of Texas
Southwestern Medical Center at Dallas

Arthur F. Ryan
Retired Chairman of the Board
and Chief Executive Officer,
Prudential Financial, Inc.

Eric M. Shooter, Ph.D.
Professor Emeritus,
Department of Neurobiology
Stanford University School of Medicine

George L. Sing
Chief Executive Officer, Stormmon, Inc. and
Managing Director, Lancet Capital

George D. Yancopoulos, M.D., Ph.D.
Executive Vice President,
Chief Scientific Officer, and President,
Regeneron Research Laboratories

Senior management team

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

George D. Yancopoulos, M.D., Ph.D.
Executive Vice President,
Chief Scientific Officer, and President,
Regeneron Research Laboratories

Murray A. Goldberg
Senior Vice President,
Finance and Administration,
Chief Financial Officer, Treasurer,
and Assistant Secretary

Stuart A. Kolinski
Senior Vice President,
General Counsel, and Secretary

Peter Powchik, M.D.
Senior Vice President,
Clinical Development

Neil Stahl, Ph.D.
Senior Vice President,
Research and Development Sciences

Robert J. Terifay
Senior Vice President,
Commercial

Daniel P. Van Plew
Senior Vice President
and General Manager,
Industrial Operations and Product Supply

Mixed Sources
FSC

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Samsung Bioepis Exhibit 1017, pg. 5445

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591
www.regeneron.com

REGENERON

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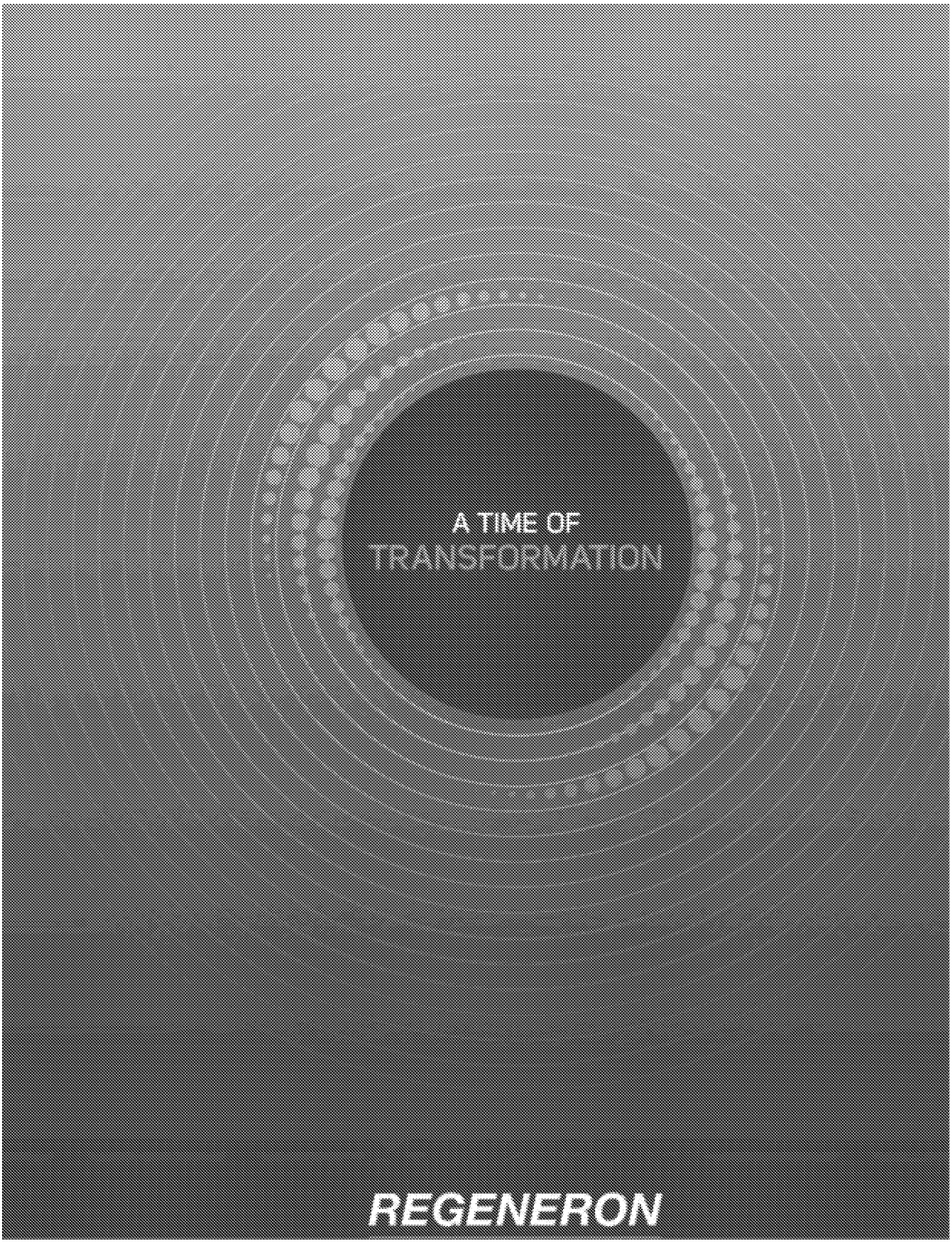

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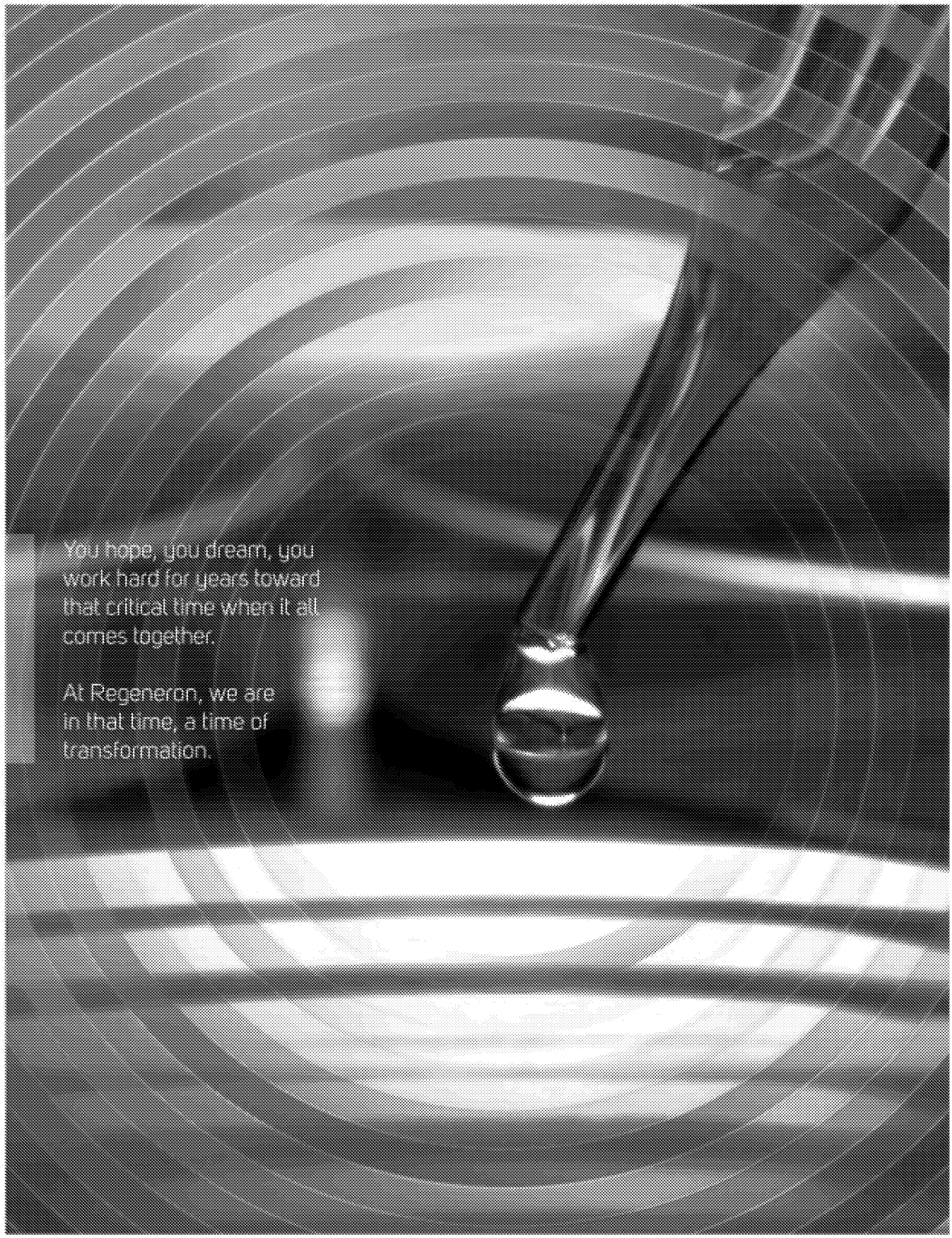

Mylan Exhibit 1017
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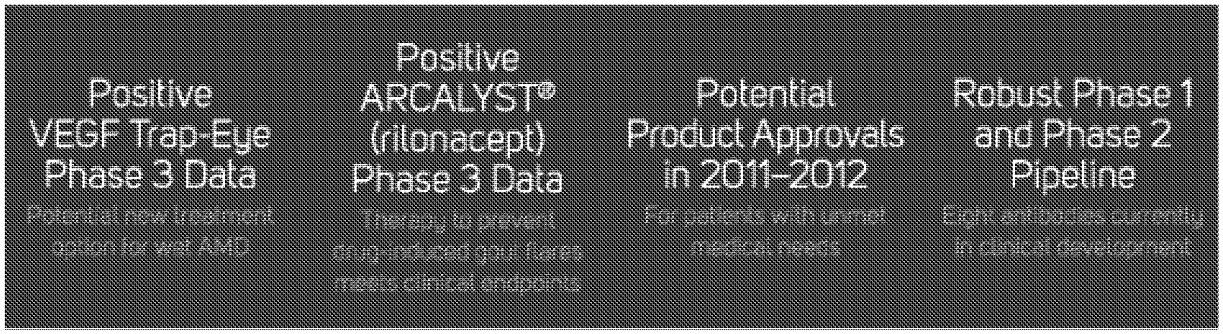
We have reached an important threshold in the transformation of our company. Positive clinical results in multiple Phase 3 programs and a focused, tenacious team



now 1,500 strong are bringing us closer to our goal of becoming a multi-product, fully integrated pharmaceutical company by delivering important medicines to patients with serious illnesses.

Mylan Exhibit 1017
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Samsung Bioepis Exhibit 1017, pg. 5449

2010 Annual Report Shareholder Letter

WE ARE TRANSFORMING INTO A COMMERCIAL ENTERPRISE

Dear Shareholders,

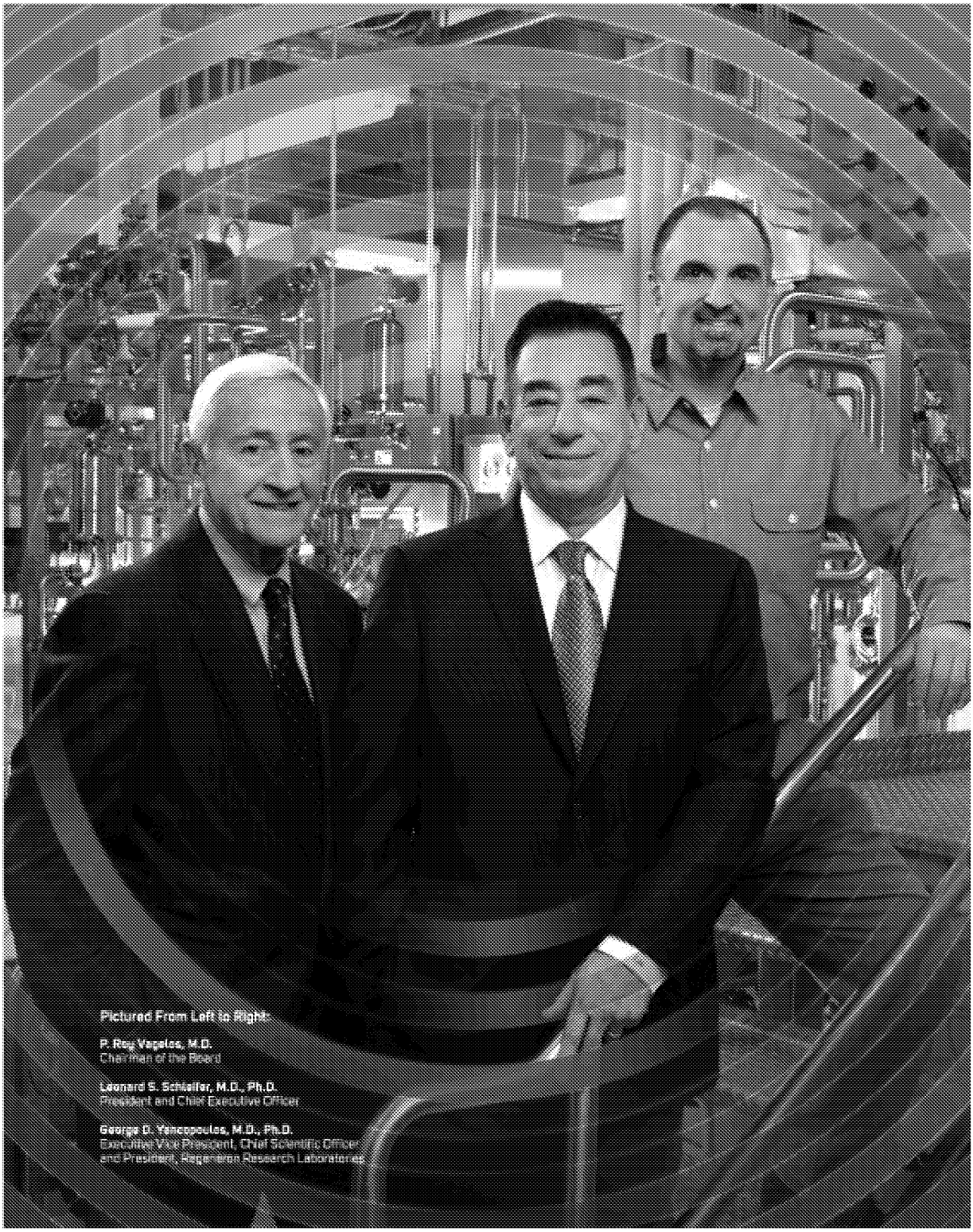
The last 12 months have been transformative and unprecedented for Regeneron.

We reported positive Phase 3 clinical results from two trials in wet age-related macular degeneration (wet AMD), the most common cause of blindness in the elderly; from three trials in gout; and from the first of two trials in another serious eye disease, central retinal vein occlusion (CRVO).

Based on these data, we submitted our application to the U.S. Food and Drug Administration (FDA) for regulatory approval of VEGF Trap-Eye in the wet AMD indication and announced our intention to submit in mid-2011 an application for FDA approval of ARCALYST® (rilonacept) for the prevention of drug treatment-induced gout flares.

We are very pleased that in April 2011 the FDA accepted our VEGF Trap-Eye filing for review and granted it Priority Review status, a designation given to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. With Priority Review, the target date for an FDA decision on our application has been set for August 20. Accordingly, if VEGF Trap-Eye is approved, we anticipate a U.S. product launch in wet AMD in the second half of 2011.

Before this annual report reaches shareholders, we expect to have released results of the second Phase 3 study we have been conducting with VEGF Trap-Eye in CRVO, and we intend to seek FDA approval for CRVO if the second Phase 3 study in this indication confirms the results of the first trial. Also imminent are results from our Phase 3 trial of aflibercept (VEGF Trap) in second-line colorectal cancer.



Pictured From Left to Right:

P. Roy Vagelos, M.D.
Chairman of the Board

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

George D. Yancopoulos, M.D., Ph.D.
Executive Vice President, Chief Scientific Officer
and President, Regeneron Research Laboratories

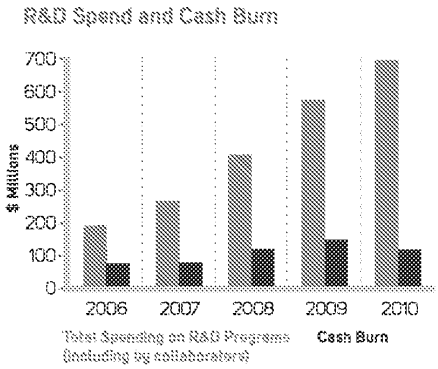
We announced in March 2011 that in the Phase 3 trial of aflibercept in second-line non-small-cell lung cancer, adding aflibercept to the chemotherapeutic agent docetaxel did not improve overall survival compared to docetaxel and placebo. Also, in February 2010, we announced that while ARCALYST® (rilonacept) was effective in preventing drug-induced gout flares in the first of our two Phase 3 trials in that indication, in another Phase 3 study it was not more effective than non-steroidal anti-inflammatory agents (NSAIDS) in treating acute gout flares once flares had started.

In the pharmaceutical industry, the journey to bring even one drug to market is long and arduous, so we are delighted to be close to the point of potentially commercializing two drugs for serious medical conditions — wet AMD and gout. Yet this is not the full story of Regeneron today. If biotechnology companies are fortunate enough to bring a drug to market after years of investment and uncertainty, then most face the tough challenge of building a pipeline that can sustain their growth. Regeneron already has that pipeline in place, with 11 compounds in various stages of clinical development. We also have the technology platforms, the personnel, and the financial resources, through our collaboration with sanofi-aventis, to advance and replenish our pipeline of fully human monoclonal antibodies.

In fact, we aim to introduce approximately 30 to 40 additional antibodies into clinical development by the end of 2017. One of the most promising programs in the pipeline today is REGN727, an antibody to a novel protein called PCSK9 that is believed to play a role in regulating production of LDL (bad) cholesterol. REGN727 is exciting because potentially it may provide an alternative for people who are unable to lower their cholesterol to recommended levels even by taking statin medications. The REGN727 program is described in further detail on page 7 of this report.

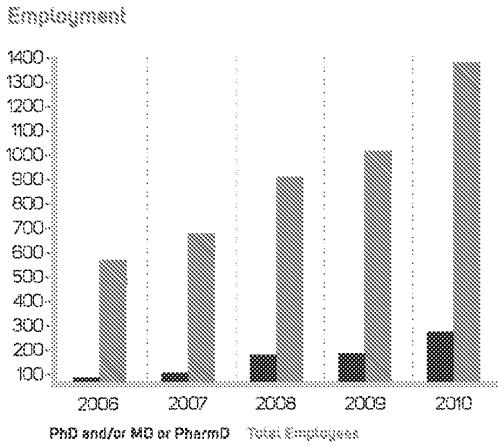
Since we entered into our antibody collaboration with sanofi-aventis in 2007, our research and clinical development program has grown to become one of the 10 largest in the biotech industry. We ourselves invested nearly $500 million on R&D in 2010. Total R&D spending on our programs, including spending by sanofi-aventis and Bayer HealthCare, our collaborator in the VEGF Trap-Eye program, climbed to almost $700 million last year.

Although our 2010 R&D spending was substantial, our use of cash — our "cash burn" in the language of the biotech industry — was only $125 million. The most important reason for this was the funding we received from our collaborators, sanofi-aventis and Bayer HealthCare. Additionally, ARCALYST® generated $20 million in product sales for its approved indication, the rare genetic disease called CAPS. Two other significant 2010 events enhanced our financial resources: we received an up-front $165 million payment from Astellas Pharma Inc. to extend its license to our VelocImmune® antibody generation technology; and we also took



advantage of favorable market conditions in October 2010 to raise $175 million through a public offering of our common stock, the first time we have gone to the public markets for capital since 2006. We ended 2010 with $627 million in cash and marketable securities.

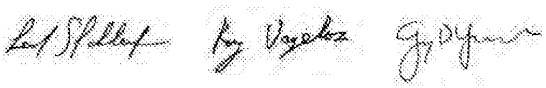
The year 2010 was also memorable in terms of organizational growth, as we increased staff by 36% to a total of about 1,400 employees. Most of the increase was in R&D to support the antibody collaboration. In the first quarter of 2011, we added over 80 more jobs and moved into a third new building at our Tarrytown campus. We currently count about 260 Ph.D.s and 50 M.D.s among our staff. The Industrial Operations and Product Supply (IOPS) department in Rensselaer is also growing. The group almost doubled production capacity in 2010 to 54,000 liters, while producing 60 lots of drug material for 11 different clinical programs. Our production facility and know-how are major — and often unrecognized — assets for Regeneron.



We have ambitious hiring targets for 2011, in large part to prepare for the potential commercialization of VEGF Trap-Eye for wet AMD and ARCALYST® for the gout flare prevention indication. We own exclusive U.S. rights to VEGF Trap-Eye and worldwide rights to ARCALYST®. We are also entitled to half of the profits from commercialization of VEGF Trap-Eye outside of the United States through our collaboration with Bayer HealthCare.

A sad event amidst the successes of the last year was the sudden death in November 2010 of our dear friend and colleague, Stuart A. Kolinski, Senior Vice President and General Counsel. Stuart, 45 years old, died the day after we reported the positive results in our two trials in wet AMD. Stuart made innumerable contributions to Regeneron during his 10 years with the company. He will be missed by all those who knew his drive, intellect, warmth, and humility.

As much as the past 12 months were a time of transformation, they were also a period of transition to new challenges: submitting a supplemental application for FDA review of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy and, potentially, for VEGF Trap-Eye in the CRVO indication; building a sales, marketing, and product distribution organization in the United States; preparing for potential product launches; and advancing our earlier-stage antibody candidates. We look forward to reporting back to you a year from now on our accomplishments in these endeavors. As always, we thank you, our shareholders, for your confidence and support.



2010 and 2011 Year-to-Date Highlights

February
We announced positive six-month data from the Phase 2 study (called DA VINCI) of VEGF Trap-Eye in patients with clinically significant diabetic macular edema (DME).

May
We reported positive proof-of-concept interim data from a Phase 1 study of the PCSK9 antibody (REGN727) for LDL (bad) cholesterol reduction and from a Phase 2 study of the nerve growth factor (NGF) antibody (REGN475) for pain.

June
We announced positive results for ARCALYST® in the first of two Phase 3 studies for the prevention of gout flares in patients initiating allopurinol therapy and unsuccessful results for ARCALYST® in treating acute gout flares once flares had started.

July
We held our first Investor Day in New York City. Nearly 200 people attended the event live or virtually on the Internet.

Astellas Pharma and Regeneron extended through 2023 Astellas' non-exclusive license to utilize the Regeneron Velocimmune® technology in its internal research programs to discover fully human monoclonal antibodies. Astellas paid the Company $165 million upfront and agreed to pay another $130 million in 2018.

October
We raised $175 million in a common stock offering, our first public financing since 2006.

November
We reported that VEGF Trap-Eye met the primary endpoint of non-inferiority to Lucentis® (ranibizumab), the market-leading anti-VEGF therapy, in the one-year analysis of two Phase 3 studies in wet age-related macular degeneration (wet AMD).

December
The U.S. FDA placed REGN475 on clinical hold following a case of avascular necrosis of a joint with another company's anti-NGF antibody.

We reported positive results for VEGF Trap-Eye in the first of two Phase 3 studies in central retinal vein occlusion and positive one-year results from the Phase 2 study in DME.

2011 Year-to-Date

February
We announced positive results for ARCALYST® in the second Phase 3 trial for the prevention of gout flares in patients initiating uric acid-lowering therapy.

We announced that three more antibodies have entered clinical development.

We submitted a Biologics License Application to the FDA for VEGF Trap-Eye for the treatment of wet AMD.

March
We announced that in the Phase 3 study of aflibercept (VEGF Trap) in second-line non-small-cell lung cancer, a regimen of aflibercept and chemotherapy did not show a survival benefit compared with chemotherapy alone.

April (up to press time)
We announced the start of a Phase 3 clinical program for VEGF Trap-Eye in DME.

We announced that the FDA has accepted for review our filing for VEGF Trap-Eye for the treatment of wet AMD, has granted the application Priority Review, and has set August 20, 2011 as the target date for an FDA decision.

Directors

P. Roy Vagelos, M.D.
Chairman of the Board. Retired Chairman of the Board and Chief Executive Officer, Merck & Co. Inc.

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Charles A. Baker
Retired Chairman of the Board,
President and Chief Executive Officer,
The Dexter Company, PLC

Michael S. Brown, M.D.
Regental Professor and Director, Jonsson Center for Molecular Genetics, The University of Texas Southwestern Medical Center at Dallas

Alfred G. Gilman, M.D., Ph.D.
Chief Scientific Officer, Cancer Prevention and Research Institute of Texas and Regental Professor of Pharmacology Emeritus, The University of Texas Southwestern Medical Center at Dallas

Joseph L. Goldstein, M.D.
Regental Professor and Chairman, Department of Molecular Genetics, The University of Texas Southwestern Medical Center at Dallas

Christine A. Poon
Dean, The Max M. Fisher College of Business at The Ohio State University, Retired Vice Chairman and Worldwide Chairman of Pharmaceuticals, Johnson & Johnson

Arthur F. Ryan
Retired Chairman of the Board and Chief Executive Officer, Prudential Financial, Inc.

Eric M. Shooter, Ph.D.
Professor Emeritus, Department of Neurobiology, Stanford University School of Medicine

George L. Sing
Chief Executive Officer, Sherman, PLC, and Managing Director, Lancet Capital

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Peter Pouletty, M.D.
Senior Vice President, Clinical Development

Neil Stahl, Ph.D.
Senior Vice President, Research and Development Sciences

Robert J. Terifay
Senior Vice President, Commercial

Daniel Van Plew
Senior Vice President and General Manager, Products Operations and Product Supply

Corporate Information

Common Stock and Related Matters
Our Common Stock is traded on The NASDAQ Global Select Market under the symbol "REGN." The Class A Stock is not publicly 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.

2009	HIGH	LOW
First Quarter	$20.18	$11.81
Second Quarter	18.42	12.31
Third Quarter	23.45	16.53
Fourth Quarter	24.97	19.02

2010	HIGH	LOW
First Quarter	$ 29.38	$ 22.49
Second Quarter	30.56	22.32
Third Quarter	27.53	23.45
Fourth Quarter	33.54	24.75

As of April 13, 2011, there were 428 shareholders of record of the Common Stock and 37 shareholders of record of the Class A Stock. The closing sales price for the Common Stock on that date was $44.76.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

Corporate Office
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707
(914) 345-7400

SEC Form 10-K
A copy of our 2010 annual report on Form 10-K filed with the Securities and Exchange Commission (which accompanies and forms part of our 2010 Annual Report to Shareholders) is available without charge from the Regeneron Investor Relations Department.

Annual Meeting
The Annual Meeting will be held on Friday, June 10, 2011 at 10:30 a.m. at the Westchester Marriott Hotel, 670 White Plains Road, Tarrytown, NY 10591.

Shareholders' Inquiries
Inquiries relating to stock transfer or lost certificates and notices of changes of address should be directed to our Transfer Agent: American Stock Transfer & Trust Co., 59 Maiden Lane, Plaza Level, New York, NY 10038, (800) 937-5449. General information regarding the Company, recent stock quotes and SEC filings are available on the web site at www.regeneron.com or can be obtained by contacting the Investor Relations Department at (914) 345-7704.

Transfer Agent and Registrar
American Stock Transfer & Trust Co.
59 Maiden Lane
Plaza Level
New York, NY 10038

Independent Registered Public Accounting Firm
PricewaterhouseCoopers LLP

This Annual Report contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements include, but are not limited to, statements relating to the timing and conduct of preclinical studies and clinical trials of our product candidates and the timing of and plans relating to regulatory filings and potential regulatory approval and commercialization of our late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our product and drug candidates, competing drugs that may be superior to our product and drug candidates, uncertainty of market acceptance of our product and drug candidates, our ability to enter collaborations, the availability and cost of capital, the costs of developing, producing and selling products, the potential of any collaborations by parties exercising our agreements with the Sanofi-Aventis Group or Bayer HealthCare, to be successful or continued or result in any product success, and risks associated with third-party intellectual property. A more complete description of these and other material risks can be found in our filings with the Securities and Exchange Commission, including our Form 10-K for the year ended December 31, 2010. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

REGENERON

Regeneron and its logo are registered trademarks of Regeneron Pharmaceuticals, Inc. All other trademarks and registered trademarks are the property of their respective owners.

Mixed Sources
Product group from well-managed forests and other controlled sources
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DEVELOPING A DEEP AND BALANCED PIPELINE

Marketed

ARCALYST® (rilonacept)
Cryopyrin-Associated Periodic Syndromes (CAPS)

BLA

VEGF Trap-Eye
Wet age-related macular degeneration

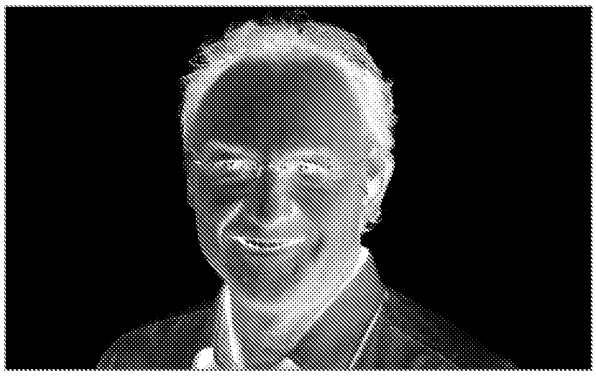
Phase 3

ARCALYST® (rilonacept)
Gout flare prevention in patients initiating uric acid-lowering therapy

VEGF Trap-Eye
Central retinal vein occlusion
Diabetic macular edema

Aflibercept (VEGF Trap)
2nd-line metastatic colorectal cancer
1st-line metastatic prostate cancer

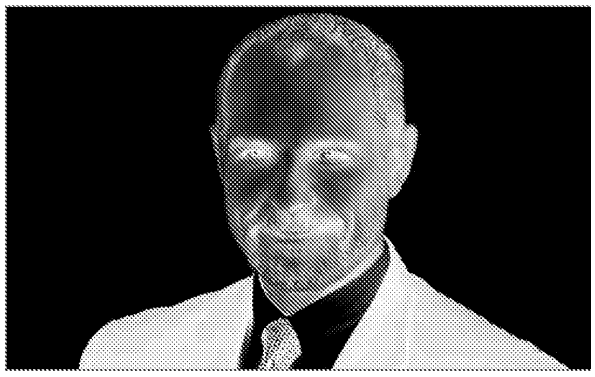
BECOMING A FULLY INTEGRATED PHARMACEUTICAL COMPANY



Neil Stahl, Ph.D.

Senior Vice President, Research and Development Sciences

"Our product candidates target a mix of validated and novel targets. Having a balanced portfolio helps manage the risk inherent in drug development."



Peter Powchik, M.D.

Senior Vice President, Clinical Development

"We have the enviable ability to add several additional fully human antibodies to the clinical pipeline each year due to the productivity of our discovery and development platforms."

Mylan Exhibit 1017
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Phase 2

Aflibercept (VEGF Trap)
1st-line metastatic colorectal cancer

REGN727 (PCSK9 Antibody)
LDL cholesterol reduction

REGN475 (NGF Antibody)*
Osteoarthritis of the knee
**On Clinical Hold*

REGN88 (IL-6R Antibody)
Rheumatoid arthritis
Ankylosing spondylitis

REGN668 (IL-4R Antibody
Eosinophilic asthma

Phase 1

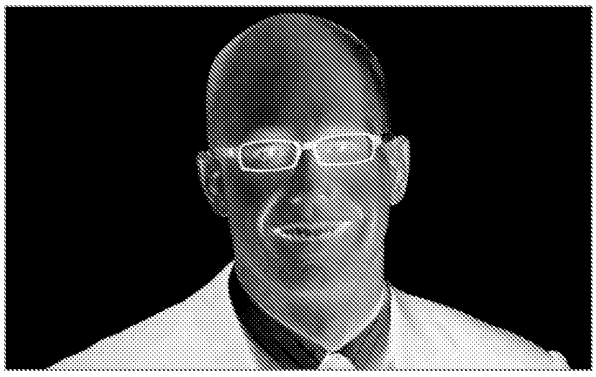
REGN421 (Dll4 Antibody)
Advanced malignancies

REGN668 (IL-4R Antibody)
Atopic dermatitis

REGN910 (ANG2 Antibody)
Cancer

REGN728
Undisclosed

REGN846
Undisclosed



Daniel P. Van Plew

Senior Vice President and General Manager, Industrial Operations and Product Supply

"We've made major investments to build the know-how and infrastructure needed to supply our drug products."

Robert J. Terifay

Senior Vice President, Commercial

"This is a very exciting time at Regeneron as we complete regulatory filings and prepare for potential product launches in wet AMD and gout."

Mylan Exhibit 1017
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Samsung Bioepis Exhibit 1017, pg. 5457

VEGF TRAP-EYE — A POTENTIAL NEW TREATMENT FOR SEVERAL SERIOUS EYE DISEASES

Uncontrolled buildup of fluid from leaky blood vessels in the macula, the light-sensitive part of the retina responsible for sharp, direct vision, can lead to irreparable damage to the macula and to vision loss. In recent years, medicines that block the activity of a blood vessel growth factor called VEGF (vascular endothelial growth factor) have not only stabilized vision in people losing their sight from these conditions, which include wet age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), and diabetic macular edema (DME); the medicines have actually restored vision in many patients by reversing the accumulation of fluid and swelling.

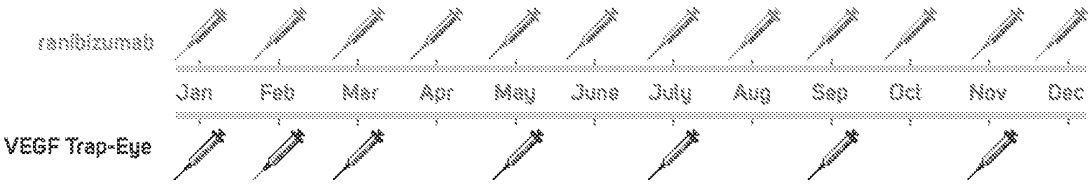
In February 2011, we submitted a regulatory application to the FDA to market our VEGF Trap-Eye drug candidate for wet AMD, the best known of these eye diseases and the leading cause of blindness in the elderly. Based on the Phase 3 clinical data, we and our collaborator, Bayer HealthCare, believe VEGF Trap-Eye is a novel anti-VEGF agent that, if approved by regulatory authorities, could be an effective therapy for the treatment of wet AMD when administered on an every two months dosing schedule. We are also encouraged by initial clinical results in CRVO and DME.

$3+ Billion | The global wet AMD market is growing > 20% annually

Phase 3 Trial Results in Wet AMD

In our two Phase 3 studies in wet AMD, 2-milligram (mg) doses of our drug candidate (VEGF Trap-Eye) given every two months achieved similar (the technical term is non-inferior) results in terms of maintaining vision to current standard-of-care anti-VEGF therapy: Lucentis® (ranibizumab) 0.5 mg dosed according to its label every four weeks. Average vision gains with the two therapies were also similar in these trials, as were the safety profiles of the two medicines.[1] Feedback from physicians we consulted suggests that treatment that requires half the dosing yet provides comparable predictable results would be a major advantage for patients. Today, many retinal specialists would like to treat patients less often than monthly but must examine them each month to determine if another treatment is needed. Monthly office visits, whether or not they result in treatments, are inconvenient for physicians and patients and burdensome for the caregiver who must bring the patient to the doctor's office because treated patients are not permitted to drive themselves home.

Phase 3 Trial Design
VEGF Trap-Eye vs. ranibizumab



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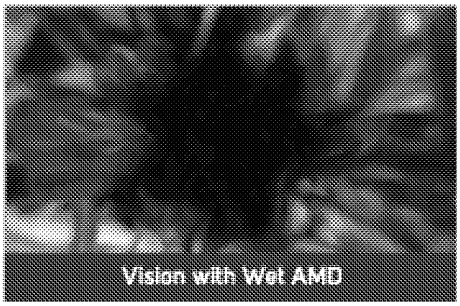
Wet AMD

There are two forms of AMD: wet and dry. The wet form is responsible for about 80% to 90% of all AMD-related blindness, and it can develop at any time in people with dry AMD. Genetic predisposition, diet, and environmental risk factors contribute to the development of AMD, but changes due to aging may be the initial stimulus. More than 210,000 Americans are newly diagnosed with and treated for wet AMD each year. Prevalence of AMD in the United States is estimated at 1.8 million people (1.2 million of whom have wet AMD), and with the aging of the Baby Boom generation, is expected to increase to nearly 3 million by 2020.



Vision with Wet AMD

Central Retinal Vein Occlusion

CRVO is triggered by a blockage of the central retinal vein, typically from a blood clot or pressure from arteries in the retina. The blockage leads to a backup of blood and fluid that injures the retina. We and our collaborator Bayer HealthCare expect soon to report results from the second of two Phase 3 clinical trials of VEGF Trap-Eye in this indication. We reported positive results from the first study, called COPERNICUS, in December 2010.

Typical Monthly Injection Procedure

Diabetic Macular Edema

Patients with diabetes are at risk of developing fluid accumulation and swelling in the macula that is thought to be mediated by the production of VEGF and other blood vessel growth factors in response to a lack of oxygen. Among Americans who have had diabetes for 10 years, the incidence of DME is estimated at 20% of patients with type 1 diabetes and 25% of patients with type 2 diabetes who use insulin. We and Bayer HealthCare initiated the first of two planned Phase 3 studies in DME in April 2011 following a positive Phase 2 trial reported in February 2010 (six-month data) and December 2010 (12-month data).

[1] The incidence of eye treatment-related side effects was balanced across all treatment groups in both studies. The most frequent events were associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse eventswere conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters.

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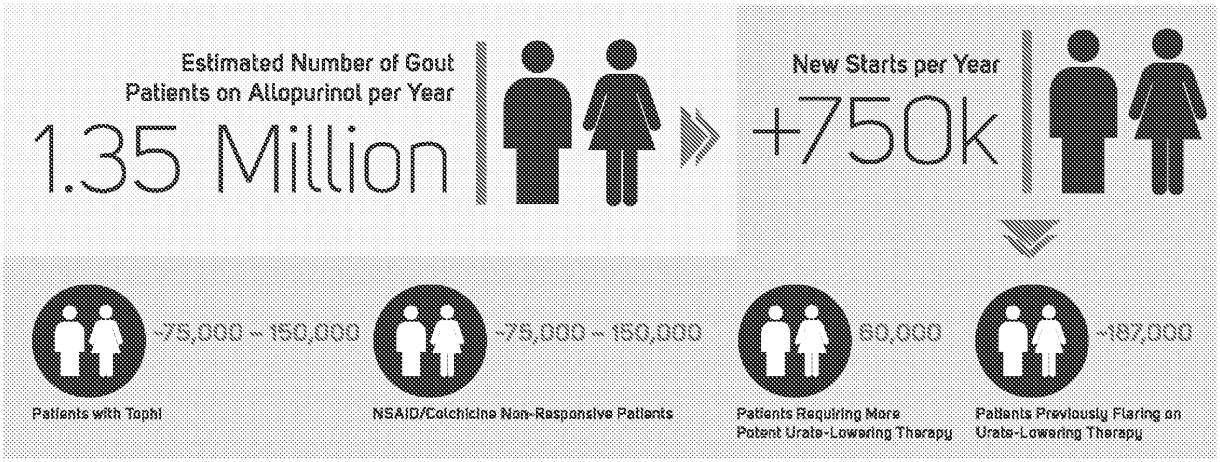
ARCALYST® (RILONACEPT) FOR PREVENTION OF DRUG-INDUCED GOUT FLARES

We Plan to File for Regulatory Review in Mid-2011

In our three Phase 3 studies, including two reported in the first quarter of 2011, all patients received a drug called allopurinol to reduce deposits of uric acid in joints, the standard approach to treating gout. The trials compared patients who were treated with allopurinol plus either a low or high dose of ARCALYST® or a placebo medicine. At both low and high doses, ARCALYST® was effective relative to placebo in preventing the occurrence of gout flares — the joint pain that is the major symptom of gout. The decrease in the mean number of flares was 73% to 80% in one trial, depending on the dose, and 72% in the second trial at both doses. The third Phase 3 study provided additional safety information. ARCALYST® was generally well tolerated in these studies. Injection site reactions, usually considered mild, were the most common side effect.

What Causes Gout?

Gout is a painful and often incapacitating form of arthritis that affects about three million Americans. Gout occurs when high blood levels of uric acid, a bodily waste product normally excreted by the kidneys, lead to the formation of crystals, typically in the toe and other joints. While allopurinol and newer uric acid-lowering medicines are often effective in reducing uric acid concentrations, many patients experience more rather than fewer flares during the first months of treatment as these medicines break down or increase the excretion of uric acid crystals from the joints into blood vessels.



Where ARCALYST® Fits in

ARCALYST® was designed to block the anti-inflammatory protein interleukin-1 (IL-1). IL-1 overproduction by infection-fighting cells in response to high concentrations of uric acid is believed to trigger acute gout flares, which generally persist for seven to 10 days. Non-steroidal anti-inflammatory agents (NSAIDs) and the drug colchicine are sometimes prescribed to manage gout flares for patients on uric acid-lowering therapy, but safety concerns and side effects limit their use. If ARCALYST® is approved by regulatory authorities, target populations will include people initiating uric acid-lowering therapy who are intolerant or unresponsive to NSAIDS or colchicine or have more severe gout, often involving protruding uric acid crystal deposits called tophi.

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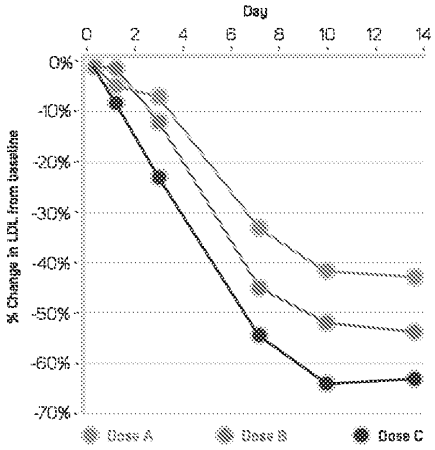
REGN727 (PCSK9 ANTIBODY)

A Novel Approach to Reducing LDL (Bad) Cholesterol

The connection between LDL (low-density lipoprotein) cholesterol, plaque buildup in arteries, and increased risk for coronary artery disease has long been known, but the optimal LDL cholesterol level for patients with or at risk of heart disease has been a moving target. Current American Heart Association (AHA) guidelines advise that LDL cholesterol not exceed 100 mg per deciliter for people at high risk for cardiac events and AHA is considering new guidelines that may push the recommended level even lower. Statin drugs, the world's best selling class of medicines, revolutionized the management of LDL cholesterol; yet a third of patients on statins fail to reach their recommended LDL level.

REGN727
Subcutaneous Single Dose Effect on LDL



Phase 1 study of 32 healthy volunteers who presented with LDL cholesterol levels above 100 mg per deciliter.

Our Early Clinical Data Are Promising

Our REGN727 antibody works on the same general chemical pathway as statins do but in a different way. Initial clinical data that we presented at the 2010 AHA meeting, as well as genetic studies, suggest that blocking PCSK9, REGN727's target protein, may be a viable new approach to managing LDL cholesterol, especially for people who do not get to their target LDL levels using statins alone and for people who do not respond to statins or cannot tolerate them.

Validation from Genetic Studies

Genetic evidence for the role of PCSK9 as a modulator of LDL cholesterol has made PCSK9 a hot target in the pharmaceutical industry today — and Regeneron, in 2010, was the first company to present clinical data for an anti-PCSK9 agent. A study published in the New England Journal of Medicine in 2006[1] showed that people who naturally produce sub-normal amounts of the PCSK9 protein due to a mutation in one of their two PCSK9-encoding genes have very low levels of LDL cholesterol and almost a 90% lower chance of developing coronary heart disease. In our initial study, a single subcutaneous dose of REGN727 reduced LDL cholesterol by over 40% to over 60%, depending on the dose. No treatment-related serious adverse events were seen.

Although our clinical experience with REGN727 remains limited, these initial results were an important proof of concept for our program. With our collaborator, sanofi-aventis, we are now conducting several Phase 2 studies, some testing REGN727 in combination with statins, others testing REGN727 alone. We hope to have initial results from one or more of these trials by the end of 2011.

[1] Hobbs, et al. March 23, 2006. New Eng. J Med. 354:1264-1272

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WHAT REGENERON EMPLOYEES HAVE TO SAY

"Working here is not an 8-hour-a-day job, but no one questions the hours because what we do here is very important and exciting."

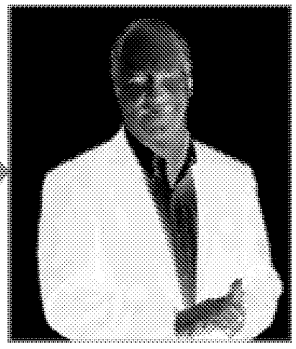
Venus Lai
Director, Transgenic Biology, VelocGene®
Tarrytown

"There is an infectious 'can do' attitude here and a feeling that there is no obstacle that can't be overcome if we work smart and work hard."

Matt Elliott
Associate Director,
Quality Control, Rensselaer

"Making new medicines! It doesn't get any better than that. You want to do the best for each patient."

Jerry Underwood
Vice President,
Technical Operations,
Rensselaer



"The attitude here is do your best and take on more responsibility."

Justin Williams
Research Associate,
Tarrytown

"Regeneron is the place to be if you truly like to be involved in developing and delivering new, innovative drugs to patients. Each employee plays a role and the opportunities for career advancement are endless."

Amy Jones
Manager,
Project Management, Rensselaer

"Don't come to work and expect the expected, because Regeneron is just not the expected. Every day is different."

Yanina Levchinsky-Grimmond
Project Manager,
Rensselaer

"At Regeneron, people who are innovative and value excellence are rewarded with opportunity."

Lori Morton
Senior Staff Scientist,
Tarrytown

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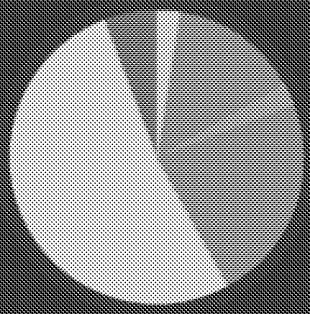


Degrees by type for Regeneron employees.

Education

M.D. | D.V.M.
3%

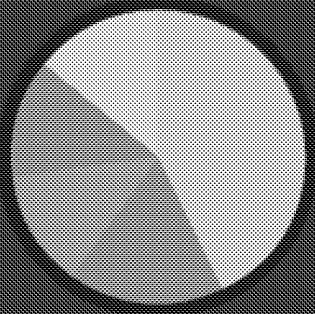
Ph.D.
14%

JD | MBA
5%

MS | MA
23%

BS | BA | BBA
52%

AA or Lesser
3%



Dedication

1 Year or Less
43%

2 Years
17%

3 – 5 Years
13%

6 – 9 Years
13%

10+ Years
14%

Countries of Origin

Regeneron employees come from many backgrounds ar nations. What we share is a commitment to excellence and to improving patients' lives.

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.

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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

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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.

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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.

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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.

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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.

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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.

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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

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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 knock-out 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.

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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-IL1β 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

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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

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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-IL1β 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.

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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

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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

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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

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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

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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

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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,

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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.

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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.

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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.

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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.

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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

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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

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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

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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.

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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.

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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.

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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-IL1β 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

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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

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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.

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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

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- 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.

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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]

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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	22.32
Third Quarter	27.53	20.45
Fourth Quarter	33.94	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.

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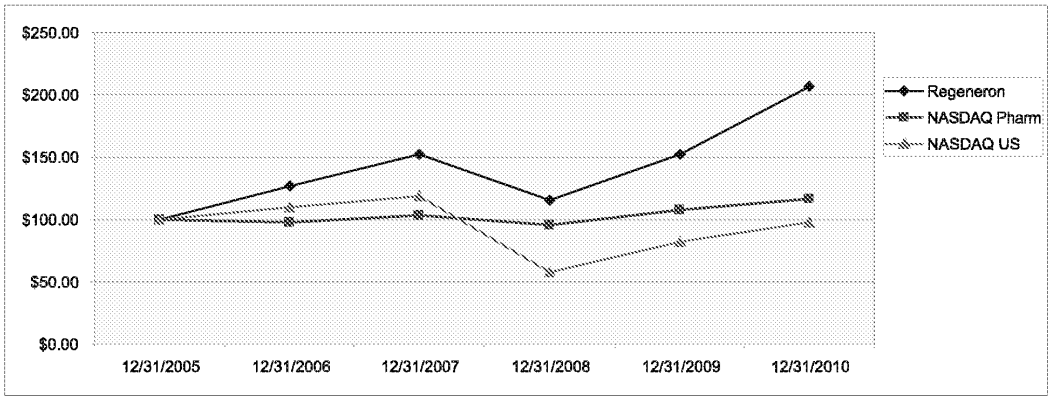
STOCK PERFORMANCE GRAPH

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

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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	$ 386,725	$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)

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	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	741,202	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.

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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.

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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

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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.

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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.

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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.

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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.

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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.

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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

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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	$380.0	$ 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

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.

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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.

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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 *(In millions)*	Year ended December 31, 2010	2009	Increase (Decrease)
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.

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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

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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

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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

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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.

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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 *(In millions)*	Year ended December 31, 2009	2008	Increase (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.

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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

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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.

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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.

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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

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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-

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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.

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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.

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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.

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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

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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.

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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

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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.

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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.

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3. Exhibits

Exhibit Number			Description
3.1	(n)	-	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.

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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

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(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.

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(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.

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* 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.

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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 Eric M. Shooter, Ph.D.	*Director*
/s/ GEORGE L. SING George L. Sing	*Director*

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REGENERON PHARMACEUTICALS, INC.

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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

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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	19,506	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	159,355	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	(1,045,563)	(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.

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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.

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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 Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount					
Balance, December 31, 2007	2,260	$2	76,592	$77	$1,253,235	$ (794,136)	$ 170	$ 459,348	
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					32,523			32,523	
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	2	21,462			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					39,897			39,897	
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.

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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.

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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

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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

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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.

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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.

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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

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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.

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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

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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

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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.

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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.

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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.

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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.

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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

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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.

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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	$434,367		$434,367	
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.

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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	372,454
Less, accumulated depreciation and amortization	(131,307)	(112,778)
	$ 347,450	$ 259,676

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.

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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

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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.

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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.

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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.

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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.

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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.

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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

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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.

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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.

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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

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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.

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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	$ 103,534	$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)

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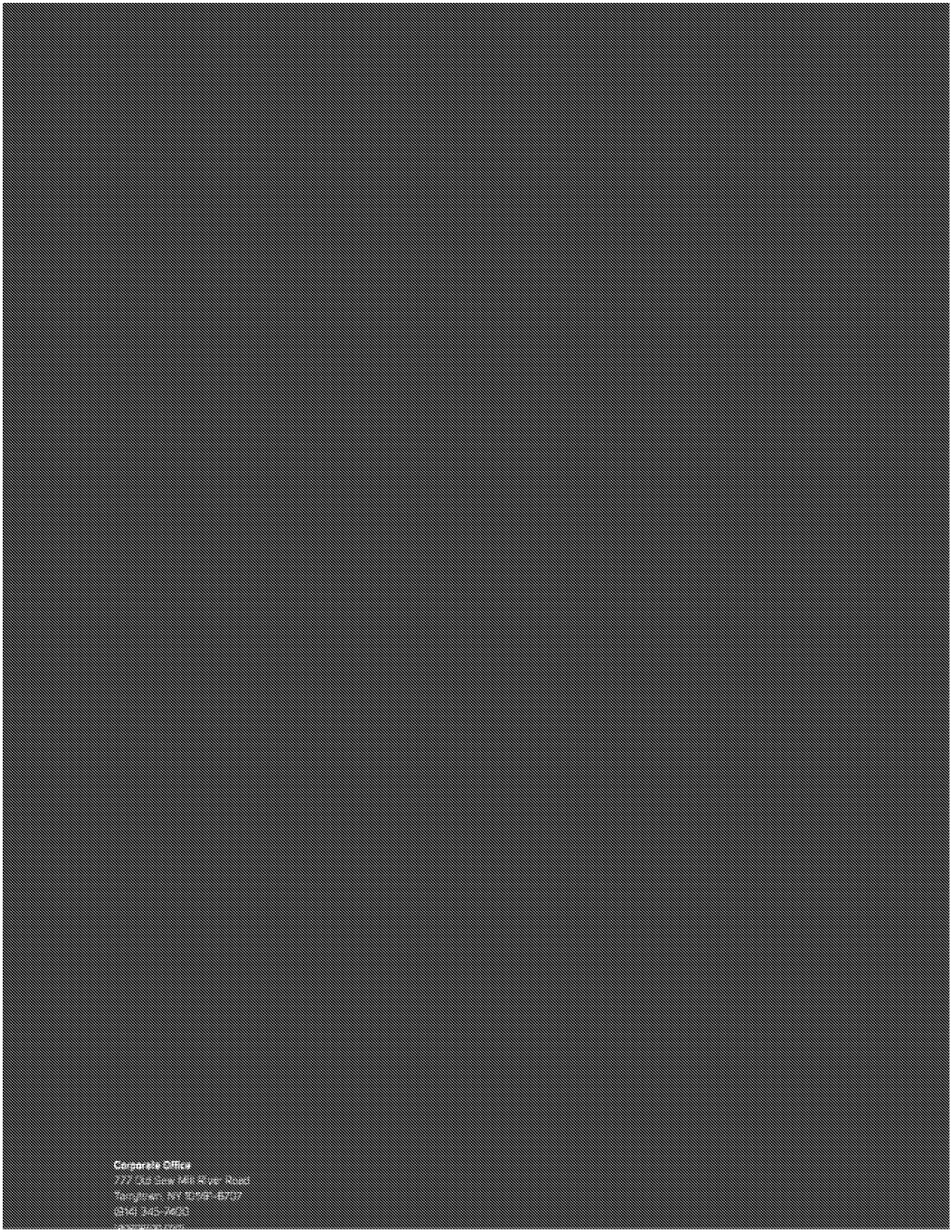

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Electronically filed 10/21/2020		
AMENDMENT UNDER 37 C.F.R. §1.111	Attorney Docket No.	REGN-008CIPCON5
	Confirmation No.	8135
	First Named Inventor	George D. Yancopoulos
	Application Number	16/397,267
	Filing Date	April 29, 2019
Address to: Mail Stop AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Group Art Unit	1647
	Examiner Name	Jon McClelland Lockard
	Title: "*Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders*"	

Sir:

This amendment is responsive to the Office Action dated May 12, 2020, for which a three-month period for response was given for response. A petition and petition fee for a three month extension of time is requested herewith making this response due by November 12, 2020. Accordingly, this response is timely filed.

In view of the remarks below and attached Terminal Disclaimers, reconsideration and allowance are respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

1. - 20. (**Canceled**)

21. (**Currently Amended**) A method for treating age related macular degeneration in a patient **in need thereof**, comprising intravitreally administering, to said patient, an effective amount of aflibercept which is 2 mg approximately every 4 weeks for the first 3 months, followed by 2 mg approximately once every 8 weeks or once every 2 months.

22. (Previously Presented) The method of claim 21, wherein the age-related macular degeneration is neovascular (wet).

23. (Previously Presented) The method of claim 21, wherein approximately every 4 weeks comprises approximately every 28 days or approximately monthly.

24. (Previously Presented) The method of claim 23, wherein the age-related macular degeneration is neovascular (wet).

25. (Previously Presented) The method of claim 22 wherein the patient loses less than 15 letters of Best Corrected Visual Acuity (BCVA) score.

26. (**Currently Amended**) The method of claim 25 wherein Best Corrected Visual Acuity (BCVA) is ~~measured by~~ **according to** Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.

27. (Previously Presented) The method of claim 22 wherein the patient gains at least 15 letters of Best Corrected Visual Acuity (BCVA) score.

28. (**Currently Amended**) The method of claim 27 wherein Best Corrected Visual Acuity (BCVA) is ~~measured by~~ **according to** Early Treatment Diabetic Retinopathy Study (ETDRS) letter

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score.

29. (**Currently Amended**) A method for treating diabetic macular edema in a patient **in need thereof**, comprising intravitreally administering, to said patient, an effective amount of aflibercept which is 2 mg approximately every 4 weeks for the first 5 injections followed by 2 mg approximately once every 8 weeks or once every 2 months.

30. (Previously Presented) The method of claim 29, wherein approximately every 4 weeks comprises approximately every 28 days or approximately monthly.

31. (Previously presented) The method of claim 29, further comprising, after 20 weeks, administering, via intravitreal injection, 2 mg of aflibercept once every 4 weeks.

32. (Previously Presented) The method of claim 29 wherein the patient loses less than 15 letters of Best Corrected Visual Acuity (BCVA) score.

33. (**Currently Amended**) The method of claim 32 wherein Best Corrected Visual Acuity (BCVA) is ~~**measured by**~~ **according to** Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.

34. (Previously Presented) The method of claim 29 wherein the patient gains at least 15 letters of Best Corrected Visual Acuity (BCVA) score.

35. (**Currently Amended**) The method of claim 34 wherein Best Corrected Visual Acuity (BCVA) is ~~**measured by**~~ **according to** Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.

36. (**Currently Amended**) A method for treating diabetic retinopathy in a patient **in need thereof**, comprising intravitreally administering, to said patient, an effective amount of aflibercept which is 2 mg approximately every 4 weeks for the first 5 injections followed by 2 mg approximately once every 8 weeks or 2 months.

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37. (Previously Presented) The method of claim 36, wherein approximately every 4 weeks comprises approximately every 28 days or approximately monthly.

38. (Previously Presented) The method of claim 36, further comprising, after 20 weeks, administering, via intravitreal injection, 2 mg of aflibercept once every 4 weeks.

39. (Previously Presented) The method of claim 36 wherein the patient loses less than 15 letters of Best Corrected Visual Acuity (BCVA) score.

40. (**Currently Amended**) The method of claim 37 wherein Best Corrected Visual Acuity (BCVA) is ~~**measured by**~~ **according to** Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.

41. (Previously Presented) The method of claim 36 wherein the patient gains at least 15 letters of Best Corrected Visual Acuity (BCVA) score.

42. (**Currently Amended**) The method of claim 41 wherein Best Corrected Visual Acuity (BCVA) is ~~**measured by**~~ **according to** Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.

43. (**Currently Amended**) A method for treating diabetic retinopathy in a patient with diabetic macular edema, **who is in need of such treatment,** comprising intravitreally administering, to said patient, an effective amount of aflibercept which is 2 mg approximately every 4 weeks for the first 5 injections followed by 2 mg approximately once every 8 weeks or 2 months.

44. (Previously Presented) The method of claim 43, wherein approximately every 4 weeks comprises approximately every 28 days or approximately monthly.

45. (Previously Presented) The method of claim 43, further comprising, after 20 weeks, administering, via intravitreal injection, 2 mg of aflibercept once every 4 weeks.

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Page 5575

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46. (Previously Presented) The method of claim 43 wherein the patient loses less than 15 letters of Best Corrected Visual Acuity (BCVA) score.

47. (**Currently Amended**) The method of claim 46 wherein Best Corrected Visual Acuity (BCVA) is ~~**measured by**~~ **according to** Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.

48. (Previously Presented) The method of claim 43 wherein the patient gains at least 15 letters of Best Corrected Visual Acuity (BCVA) score.

49. (**Currently Amended**) The method of claim 48 wherein Best Corrected Visual Acuity (BCVA) is ~~**measured by**~~ **according to** Early Treatment Diabetic Retinopathy Study (ETDRS) letter score.

50. (**Currently Amended**) A method for treating an angiogenic eye disorder in a patient **in need thereof**, said method comprising administering to the patient an effective sequential dosing regimen of a single initial dose of a VEGF antagonist, followed by one or more secondary doses of the VEGF antagonist, followed by one or more tertiary doses of the VEGF antagonist;

wherein each secondary dose is administered 4 weeks after the immediately preceding dose; and

wherein each tertiary dose is administered 8 weeks after the immediately preceding dose;

wherein the VEGF antagonist is a receptor-based chimeric molecule comprising

an immunoglobin-like (Ig) domain 2 of a first VEGF receptor **which is VEGFR1** and an Ig domain 3 of a second VEGF receptor **which is VEGFR2**, and a multimerizing component.

51. (**Cancelled**)

52. (Previously Presented) The method of claim 50 wherein the VEGF antagonist is aflibercept.

53. (**Currently Amended**) The method of claim **50** ~~**51**~~, wherein all doses of the VEGF

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antagonist are administered to the patient by intraocular administration.

54. (Previously Presented) The method of claim 53, wherein the intraocular administration is intravitreal administration.

55. (Previously Presented) The method of claim 54, wherein all doses of the VEGF antagonist comprise from about 0.5 mg to about 2 mg of the VEGF antagonist.

56. (Previously Presented) The method of claim 55, wherein all doses of the VEGF antagonist comprise 0.5 mg of the VEGF antagonist.

57. (Previously Presented) The method of claim 55, wherein all doses of the VEGF antagonist comprise 2 mg of the VEGF antagonist.

58. (**Currently Amended**) The method of claim **50** ~~51~~, wherein the angiogenic eye disorder is selected from the group consisting of: age related macular degeneration, diabetic retinopathy, diabetic macular edema, central retinal vein occlusion, branch retinal vein occlusion, and corneal neovascularization.

59. (**Currently Amended**) The method of claim **50** ~~51~~ wherein the angiogenic eye disorder is age related macular degeneration.

60. (**Currently Amended**) The method of claim **50** ~~51~~ wherein the angiogenic eye disorder is diabetic retinopathy.

61. (**Currently Amended**) The method of claim **50** ~~51~~, wherein the angiogenic eye disorder is diabetic macular edema.

62. (Previously Presented) The method of claim 59 wherein all doses of VEGF antagonist comprise 0.5 mg of the VEGF antagonist.

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63. (Previously Presented) The method of claim 59 wherein all doses of VEGF antagonist comprise 2.0 mg of the VEGF antagonist.

64. (**New**) The method of claim 24 wherein exclusion criteria for the patient include (1) active intraocular inflammation; or (2) active ocular or periocular infection.

65. (**New**) The method of claim 29 wherein exclusion criteria for the patient include (1) active intraocular inflammation; or (2) active ocular or periocular infection.

66. (**New**) The method of claim 36 wherein exclusion criteria for the patient include (1) active intraocular inflammation; or (2) active ocular or periocular infection.

67. (**New**) The method of claim 43 wherein exclusion criteria for the patient include (1) active intraocular inflammation; or (2) active ocular or periocular infection.

68. (**New**) The method of claim 52 wherein exclusion criteria for the patient include (1) active intraocular inflammation; or (2) active ocular or periocular infection.

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REMARKS

Formal Matters

Claims 21-50 and 52-68 remain pending.

Claims 1-20 were previously canceled and claim 51 is canceled here without prejudice.

Claims 21, 26, 28, 29, 33, 35, 36, 40, 42, 43, 47, 49, 50, 53 and 58-61 have been amended. Support for the amended claims can be found throughout the originally filed specification.

New claims 64-68 have been added. Support for the newly added claims can be found through the originally filed specification.

No new matter has been added.

Statement under 37 C.F.R. §§1.56 and 1.2

Applicants hereby advise the Examiner of the status of a co-pending application in compliance with the Applicant's duty to disclose under 37 C.F.R. §§1.56 and 1.2 (see also MPEP §2001.06(b)) as discussed in *McKesson Info. Soln. Inc., v. Bridge Medical Inc.*, 487 F.3d 897; 82 USPQ2d 1865 (Fed. Cir. 2007).

The Applicant wishes to bring to the Examiner's attention U.S. Patent Application No. 13/940,370, filed July 12, 2013 which issued on February 9, 2016 as U.S. Patent 9,254,338.

The Applicant wishes to bring to the Examiner's attention U.S. Patent Application No. 14/972,560, filed December 17, 2015 which issued on June 6, 2017 as U.S. Patent No. 9,669,069.

The Applicant wishes to bring to the Examiner's attention U.S. Patent Application No. 15/471,506, filed March 28, 2017 which issued on November 20, 2018 as U.S. Patent No. 10,130,681.

The Applicant wishes to bring to the Examiner's attention co-pending U.S. Patent Application No. 16/055,847, filed August 6, 2018 for which a Notice of Allowance was mailed on July 22, 2020 and the Issue Fee was paid on October 8, 2020.

The Applicant wishes to bring to the Examiner's attention co-pending U.S. Patent Application No. 16/159,282, filed October 12, 2018 for which a Notice of Allowance was mailed on July 22, 2020 and the Issue Fee was paid on October 8, 2020.

The Applicant wishes to bring to the Examiner's attention co-pending U.S. Patent Application No. 17/072,417, filed October 16, 2020 for which no actions have yet been mailed.

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These documents are available on PAIR, and thus are not provided with this communication. Please inform the undersigned if there is any difficulty in obtaining the documents from PAIR.

Non-Statutory Double Patenting

Claims 21-63 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 9,254,338.

Claims 21-63 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 9,669,069.

Claims 21-63 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 10,130,681.

Claims 21-63 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 32-42 of co-pending U.S. Patent Application Serial No. 16/159,282.

Applicants do not acquiesce to the validity of any of these rejections. However, purely to expedite prosecution, applicants have attached hereto two (2) Terminal Disclaimers with respect to the three patents and one application thereby rendering the rejections moot.

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CONCLUSION

Applicants submit that all the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees up to a strict limit of $3,000.00 beyond that authorized on the credit card, but not more than $3,000.00 in additional fees due with any communication for the above referenced patent application, including but not limited to any necessary fees for extensions of time, or credit any overpayment of any amount to Deposit Account No. 50-0815, order number REGN-008CIPCON5.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: October 21, 2020

By: /Karl Bozicevic, Reg. No. 28,807/
Karl Bozicevic
Reg. No. 28,807

Attachment: (1) Terminal Disclaimer re three patents
(2) Terminal Disclaimer re one patent application

BOZICEVIC, FIELD & FRANCIS LLP
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TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION	Docket Number (Optional) **REGN-008CIPCON5**

In re Application of: **Yancopoulos, George D.**

Application No.: **16/397,267**

Filed: **April 29, 2019**

For: **Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders**

The owner, **Regeneron Pharmaceuticals, Inc.**, of **100%** percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number **16/159,282**, filed **October 12, 2018**, as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said **reference** application, "as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application," in the event that: any such patent: granted on the pending **reference** application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 28,807

/Karl Bozicevic, Reg. No. 28,807/	**21 October 2020**
Signature	Date

Karl Bozicevic, Reg. No. 28,807
Typed or printed name

650-833-7735
Telephone Number

☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Patent Application Fee Transmittal

Application Number:	16397267
Filing Date:	29-Apr-2019
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Filer:	Karl Bozicevic/Kimberly Zuehlke
Attorney Docket Number:	REGN-008CIPCON5

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	4	100	400
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 3 months with $0 paid	1253	1	1480	1480
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	1814	2	170	340
		Total in USD ($)		**2220**

Electronic Acknowledgement Receipt	
EFS ID:	40910333
Application Number:	16397267
International Application Number:	
Confirmation Number:	8135
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Customer Number:	96387
Filer:	Karl Bozicevic/Kimberly Zuehlke
Filer Authorized By:	Karl Bozicevic
Attorney Docket Number:	REGN-008CIPCON5
Receipt Date:	21-OCT-2020
Filing Date:	29-APR-2019
Time Stamp:	19:22:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$2220
RAM confirmation Number	E20200KJ22388458
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		0725-US06_Amendment_2020-10-21_REGN-008CIPCON5.pdf	74865 7472384404 6d184fe4661b33d06ac13a83da0a64	yes	10
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		8	10	
Warnings:					
Information:					
2	Terminal Disclaimer Filed	REGN-008CIPCON5_2020-10-21_Terminal_Disclaimer_Prior_Pat.pdf	25062 16365b1b9b8a1408feea6b454407536143ee8a4d	no	1
Warnings:					
Information:					
3	Terminal Disclaimer Filed	REGN-008CIPCON5_2020-10-21_Terminal_Disclaimer_Prv_Appln.pdf	25250 3a7651382620d19c69d7220bc0e8c4435681abe4	no	1
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	34534 42e8238b7abea613625542194941c95733a9bf6d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	159711		

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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) **REGN-008CIPCON5**

In re Application of: **Yancopoulos, George D.**

Application No.: **16/397,267**

Filed: **April 29, 2019**

For: **Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders**

The owner, **Regeneron Pharmaceuticals, Inc.**, of **100%** percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** Nos. **9,254,338; 9,669,069;** and **10,130,681** as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patents** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patents**, "as the term of said **prior patents** is presently shortened by any terminal disclaimer," in the event that said **prior patents** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

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1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 28,807

/Karl Bozicevic, Reg. No. 28,807/	**21 October 2020**
Signature	Date

Karl Bozicevic, Reg. No. 28,807
Typed or printed name

650-833-7735
Telephone Number

☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/397,267	Filing Date 04/29/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	10/21/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 47	Minus	** 43	= 4		x $100 =	400
	Independent (37 CFR 1.16(h))	* 5	Minus	*** 5	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	400

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/ERIC A DANTZLER/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
* 16/397,267 *	16/397,267	YANCOPOULOS, George D.	
	Examiner	Art Unit	
	LOCKARD, JON MCCLELLAND	1647	

Document Code - DISQ	Internal Document - DO NOT MAIL

TERMINAL DISCLAIMER	☑ APPROVED	☐ DISAPPROVED
Date Filed: **21 October 2020**	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:

/JEAN PROCTOR/

Technology Center: OPLC

Telephone: (571)272-1040

2 td's

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Page 5590

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NOTICE OF ALLOWANCE AND FEE(S) DUE

96387 7590 11/12/2020

Regeneron - Bozicevic, Field & Francis
201 REDWOOD SHORES PARKWAY
SUITE 200
REDWOOD CITY, CA 94065

EXAMINER
LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/12/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/397,267	04/29/2019	George D. YANCOPOULOS	REGN-008CIPCON5	8135

TITLE OF INVENTION: USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	02/12/2021

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PTOL-85 (Rev. 02/11)

Mylan Exhibit 1017
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Page 5591

Samsung Bioepis Exhibit 1017, pg. 5591

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

96387 7590 11/12/2020

Regeneron - Bozicevic, Field & Francis
201 REDWOOD SHORES PARKWAY
SUITE 200
REDWOOD CITY, CA 94065

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/397,267	04/29/2019	George D. YANCOPOULOS	REGN-008CIPCON5	8135

TITLE OF INVENTION: USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	02/12/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
LOCKARD, JON MCCLELLAND	1647	424-134100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1_____
2_____
3_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/397,267	04/29/2019	George D. YANCOPOULOS	REGN-008CIPCON5	8135

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REDWOOD CITY, CA 94065

EXAMINER	
LOCKARD, JON MCCLELLAND	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/12/2020

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 02/11)

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OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	**Application No.** 16/397,267	**Applicant(s)** YANCOPOULOS, George D.	
	Examiner JON M LOCKARD	**Art Unit** 1647	**AIA (FITF) Status** No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the Amendment filed 21 October 2020.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are See Continuation Sheet . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☑ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/J.L/ Examiner, Art Unit 1647	/CHRISTINE J SAOUD/ Primary Examiner, Art Unit 1647

Mylan Exhibit 1017
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Page 5595

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Continuation of 3. The allowed claim(s) is/are: 21-50 and 52-68 (renumbered as claims 1-2,7-8,3-6,10-16,18 -19,21-22,20,23-24,26-32,34-35,37-43,46-47,44-45,9,17,25,33 and 36, respectively)

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

2. The Amendment filed 21 October 2020 has been received and entered in full. Claims 21, 26, 28-29, 33, 35-36, 40, 42-43, 47, 49-50, 53 and 58-61 have been amended, claim 451 has been cancelled, and claims 64-68 have been added. Newly presented claims 64-68 will be examined as they fit under the rubric of the elected invention. Therefore, claims 21-50 and 52-68 are pending and the subject of this Office Action.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 30 June 2020 and 16 July 2020 have been considered by the examiner.

Terminal Disclaimer

5. The terminal disclaimers filed on 21 October 2020 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **U.S. Patent Application Nos. 9,254,338, 9,669,069 and 10,130,681, and U.S. Patent Application No. 16/159,282** have been reviewed and are accepted. The terminal disclaimers have been recorded.

Withdrawn Objections and/or Rejections

6. The rejection of claims 21-63 on the ground of nonstatutory obviousness-type double patenting as set forth at pp. 2-6 of the previous Office action (mailed 12 May 2020) is withdrawn in view of Applicant's submission of a terminal disclaimer, and the cancellation of claim 51 (filed 21 October 2020).

Summary

7. Claims 21-50 and 52-68 are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joanne Hama**, can be reached on **(571) 272-2911**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647

/J.L/
Examiner, Art Unit 1647
November 2, 2020

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/397,267	YANCOPOULOS, George D.
	Examiner	Art Unit
	JON M LOCKARD	1647

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
NONE		05/06/2020	JML

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST (USPAT, US-PGPUB, EPO, DERWENT): See attached search history.	05/06/2020	JML
STN (MEDLINE, SCISEARCH, EMBASE, BIOSIS): See attached search history.	05/06/2020	JML
PALM: Inventor search.	05/06/2020	JML

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	EAST (USPAT, US-PGPUB, EPO, DERWENT): See attached search history.	11/02/2020	JML
	PALM: Inventor search.	11/02/2020	JML

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/397,267	YANCOPOULOS, George D.
	Examiner	**Art Unit**
	JON M LOCKARD	1647

CPC							
Symbol						**Type**	**Version**
A61K	/	38	/	179		F	2013-01-01
C07K	/	16	/	22		I	2013-01-01
C07K	/	14	/	71		I	2013-01-01
A61K	/	9	/	0048		I	2013-01-01
A61K	/	2039	/	505		A	2013-01-01
C07K	/	2319	/	30		A	2013-01-01
C07K	/	2319	/	32		A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

/JON M LOCKARD/ Examiner, Art Unit 1647	02 November 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	47	
/CHRISTINE J SAOUD/ Primary Examiner, Art Unit 1647	06 November 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20201102

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/397,267	YANCOPOULOS, George D.
	Examiner	**Art Unit**
	JON M LOCKARD	1647

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61K	/	38	/	17	
C07K	/	14	/	71	
C07K	/	19	/	00	

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

/JON M LOCKARD/ Examiner, Art Unit 1647	02 November 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	47	
/CHRISTINE J SAOUD/ Primary Examiner, Art Unit 1647	06 November 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20201102

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/397,267	YANCOPOULOS, George D.
	Examiner	**Art Unit**
	JON M LOCKARD	1647

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	21	11	30	22	39	31	48	42	58	33	67				
2	22	12	31	20	40	32	49	43	59	36	68				
7	23	13	32	23	41	34	50	46	60						
8	24	14	33	24	42	35	52	47	61						
3	25	15	34	26	43	37	53	44	62						
4	26	16	35	27	44	38	54	45	63						
5	27	18	36	28	45	39	55	9	64						
6	28	19	37	29	46	40	56	17	65						
10	29	21	38	30	47	41	57	25	66						

/JON M LOCKARD/ Examiner, Art Unit 1647	02 November 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	47	
/CHRISTINE J SAOUD/ Primary Examiner, Art Unit 1647	06 November 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20201102

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Inventor Information for 16/397267

/J.L./

Inventor Name	City	State/Country
YANCOPOULOS, GEORGE D.	YORKTOWN HEIGHTS	NEW YORK

Appln Info | Contents | Petition Info | Atty/Agent Info | Continuity Data | Foreign Data | **Inventors** | Applicants | Address | Fees | Post Info | Pre Grc

Search Another: Application # Search **or Patent #** Search **or International Registration #** Search

PCT / / Search **or PG PUBS #** Search

Attorney Docket # Search

Bar Code # Search

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EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2,688	(flt1 or vegfr1 or (vegf adj r1)) same ((flk1 or kdr or vegfr2 or (vegf adj r2)) or (Flt4 vegfr3 or (vegf adj r3)))	USPAT	OR	ON	2020/11/02 21:43
L2	676	l1 and ((chimer$ or fusion) same vegf)	USPAT	OR	ON	2020/11/02 21:43
L3	247	l1 same ((chimer$ or fusion) same vegf)	USPAT	OR	ON	2020/11/02 21:43
L4	2,629	(flt1 or vegfr1 or (vegf adj r1)) with ((flk1 or kdr or vegfr2 or (vegf adj r2)) or (Flt4 vegfr3 or (vegf adj r3)))	USPAT	OR	ON	2020/11/02 21:44
L5	126	l4 with ((chimer$ or fusion) with vegf)	USPAT	OR	ON	2020/11/02 21:44
L6	915	(l4 "l58") and ((eye or ocular or retina$ or macular) with disorder)	USPAT	OR	ON	2020/11/02 21:44
L7	855	(l4 l5) and ((eye or ocular or retina$ or macular) with disorder)	USPAT	OR	ON	2020/11/02 21:44
L8	115	(l3 l5) and ((eye or ocular or retina$ or macular) with disorder)	USPAT	OR	ON	2020/11/02 21:45
L9	10	(l3 l5) same ((eye or ocular or retina$ or macular) with disorder)	USPAT	OR	ON	2020/11/02 21:46
L10	162	yancopoulos-g$.in.	USPAT	OR	ON	2020/11/02 21:46
L11	22	l8 and l10	USPAT	OR	ON	2020/11/02 21:46
L12	6	l11 and (eye ocular macular).clm.	USPAT	OR	ON	2020/11/02 21:46

11/2/2020 9:47:03 PM
C:\Users\jlockard\Documents\EAST\Workspaces\16397267.wsp

Receipt date: 06/30/2020

INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	16/397,267
				Filing Date	April 29, 2019
				First Named Inventor	George D. Yancopoulos
				Art Unit	1647
				Examiner Name	Jon McClelland Lockard
Sheet	1	of	2	Attorney Docket Number	REGN-008CIPCON5

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Examiner Initial*	Cite No.	Patent Number Number-Kind Code (*if known*)	Issue Date YYYY-MM-DD	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	2				

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	1	Bayer Investor News, "VEGF Trap-Eye: New Data Confirm Successes in the Treatment of Age-related Macular Degeneration" (September 28, 2008)	
	2	Regeneron Press Release "Positive Interim Phase 2 Data Reported For VEGF Trap-Eye In Age-Related Macular Degeneration" (March 27, 2007)	
	3	Regeneron Press Release "VEGF TRAP-Eye Phase 2 Wet AMD Results Reported At Arvo Annual Meeting" (May 9, 2007)	
	4	Regeneron Press Release "Regeneron Reports Second Quarter Financial And Operating Results" (August 1, 2007)	
	5	Regeneron Pharmaceuticals, Inc., "Regeneron and Bayer Healthcare Initiate Phase 3 Global Development Program for VEGF Trap-Eye In Wet Age-Related Macular Degeneration (AMD)" (August 2, 2007)	
	6	Regeneron Press Release "Regeneron Announces Positive Primary Endpoint Results From A Phase 2 Study Of VEGF Trap-Eye In Age-Related Macular Degeneration" (October 1, 2007)	
	7	Regeneron Press Release "Regeneron Reports Fourth Quarter And Full Year 2007 Financial And Operating Results" (February 27, 2008)	
	8	Regeneron Pharmaceuticals, Inc., "Regeneron and Bayer HealthCare Announce Encouraging 32-Week Follow-up Results from a Phase 2 Study of VEGF Trap-Eye in Age-Related Macular Degeneration" (April 28, 2008)	
	9	Regeneron Pharmaceuticals, Inc., "Regeneron and Bayer HealthCare Announce VEGF Trap-Eye Achieved Durable Improvement in Vision over 52 Weeks in a Phase 2 Study in Patients with Age-related Macular Degeneration" (August 19, 2008)	

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	10	Regeneron Pharmaceuticals, Inc. "Regeneron Reports Full Year and Fourth Quarter 2008 Financial and Operating Results" (February 26, 2009)	
	11	Regeneron Pharmaceuticals, Inc. "Bayer and Regeneron Extend Development Program for VEGF Trap-Eye to Include Central Retinal Vein Occlusion" (April 30, 2009)	
	12	Regeneron Press Release "First Patient Enrolled In Regeneron And Bayer Healthcare VEGF Trap-Eye Phase 3 Program In Central Retinal Vein Occlusion" (July 23, 2009)	
	13	Regeneron Press Release "Regeneron Schedules November 22, 2010 Teleconference And Webcast To Discuss Results Of Two Phase 3 Studies With VEGF Trap-Eye In Wet Age-Related Macular Degeneration" (November 19, 2010)	
	14	Regeneron Press Release "Regeneron And Bayer Start Phase 3 Trial To Extend Ophthalmology Research & Development Program For VEGF Trap-Eye In Asia" (January 18, 2011)	
	15	Regeneron Press Release "Regeneron To Webcast Investor Briefing On VEGF Trap-Eye Clinical Program On Sunday, February 13th At 9 Am Et" (February 9, 2011)	
	16	Regeneron Press Release "Regeneron Submits Biologics License Application To FDA For VEGF Trap-Eye For Treatment Of Wet Age-Related Macular Degeneration" (February 22, 2011)	
	17	Regeneron Press Release "Regeneron And Bayer Announce Start Of Phase 3 Clinical Program In Diabetic Macular Edema" (April 8, 2011)	
	18	Regeneron Pharmaceuticals, Inc., "FDA Grants Priority Review for VEGF Trap-Eye for the Treatment of Wet Age-Related Macular Degeneration" (April 18, 2011)	
	19	Regeneron Press Release "VEGF Trap-Eye Submitted for EU Marketing Authorization for Treatment of Wet Age-Related Macular Degeneration (June 7, 2011)"	
	20	Regeneron Pharmaceuticals, Inc., "Regeneron Announces EYLEA™ (aflibercept ophthalmic solution) Receives Unanimous Recommendation for Approval for Treatment of Wet AMD from FDA Advisory Committee" (June 17, 2011)	
	21	Regeneron Press Release "Regeneron Announces Clinical Presentations at ASRS 2011 Annual Meeting" (August 17, 2011)	
	22	Regeneron Pharmaceuticals, Inc., "Regeneron Announces FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration: CORRECTED (November 18, 2011)	
	23	Regeneron Pharmaceuticals, Inc., "Regeneron and Bayer Initiate Phase 3 Clinical Program for the Treatment of Wet Age-Related Macular Degeneration in China" (November 28, 2011)	
	24	Regeneron Pharmaceuticals, Inc., "Two Year Results of Phase 3 Studies with EYLEA™ (aflibercept) Injection in wet AMD Show Sustained Improvement in Visual Acuity" (December 5, 2011)	

Examiner Signature	/JON M LOCKARD/	Date Considered	11/02/2020

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	1	2019/0290725	2019-09-26	Vitti et al.	

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	1	WO 2004/106378 A2	2004-12-09	Regeneron Pharmaceuticals, Inc.		
	2	WO 2005/000895 A2	2005-01-05	Regeneron Pharmaceuticals, Inc.		

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	1	BENZ et al. "CLEAR-IT-2: Interim Results Of The Phase II, Randomized, Controlled Dose- and Interval-ranging Study Of Repeated Intravitreal VEGF Trap Administration In Patients With Neovascular Age-related Macular Degeneration (AMD)" ARVO Annual Meeting Abstract (May 2007)	
	2	DO et al. "Results of a Phase 1 Study of Intravitreal VEGF Trap in Subjects with Diabetic Macular Edema: The CLEAR-IT DME Study" ARVO Annual Meeting Abstract (May 2007)	
	3	DO et al. "VEGF Trap-Eye Vision-specific Quality of Life through 52 Weeks in Patients with Neovascular AMD in CLEAR-IT 2: A Phase 2 Clinical Trial" ARVO Annual Meeting Abstract (April 2009)	
	4	HALLER et al., "VEGF Trap-Eye In CRVO: Primary Endpoint Results of the Phase 3 COPERNICUS Study" ARVO Annual Meeting Abstract (April 2011)	
	5	HEIER et al., "CLEAR-IT 2: Phase 2, Randomized Controlled Dose and Interval-Ranging Study of Intravitreal VEFG Trap Eye in Patients with Neovascular Age-Related Macular Degeneration: Predictive Factors for Visual Acuity" ARVO Annual Meeting Abstract (April 2009)	
	6	HEIER et al., "The 1-year Results of CLEAR-IT 2, a Phase 2 Study of Vascular Endothelial Growth Factor Trap-Eye Dosed As-needed After 12-week Fixed Dosing" Ophthalmology 2011;118:1098–1106 (June 2011)	
	7	HEIER et al., "The 1-year Results of CLEAR-IT 2, a Phase 2 Study of Vascular Endothelial Growth Factor Trap-Eye Dosed As-needed After 12-week Fixed Dosing: Erratum" Ophthalmology 2011;118:1700 (September 2011)	
	8	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00320775 "Safety and Tolerability of Intravitreal Administration of VEGF Trap in Patients With Neovascular Age-Related Macular Degeneration" 70 pages, Latest version submitted June 8, 2011 on ClinicalTrials.gov (NCT00320775_2006-2011)	

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	9	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00320775 "Safety and Tolerability of Intravitreal Administration of VEGF Trap in Patients With Neovascular Age-Related Macular Degeneration" 10 pages, Latest version submitted March 16, 2015 on ClinicalTrials.gov (NCT00320775_2015)	
	10	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00320788 "Safety and Efficacy of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor (VEGF) Trap in Patients With Wet Age-Related Macular Degeneration (AMD)" 71 pages, Latest version submitted December 1, 2011 on ClinicalTrials.gov (NCT00320788_2006-2011)	
	11	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00320788 "Safety and Efficacy of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor (VEGF) Trap in Patients With Wet Age-Related Macular Degeneration (AMD)" 31 pages, Latest version submitted January 27, 2012 on ClinicalTrials.gov (NCT00320788_2012)	
	12	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00320814 "Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema" 30 pages, Latest version submitted June 8, 2011 on ClinicalTrials.gov (NCT00320814_2006-2011)	
	13	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00509795 "Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)" 318 pages, Latest version submitted December 1, 2011 on ClinicalTrials.gov (NCT00509795_2007-2011)	
	14	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00509795 "Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)" 200 pages, Latest version submitted December 20, 2012 on ClinicalTrials.gov (NCT00509795_2012)	
	15	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00527423 "Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD" 64 pages, Latest version submitted November 1, 2011 on ClinicalTrials.gov (NCT00527423_2007-2011)	
	16	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00527423 "Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD" 42 pages, Latest version submitted June 10, 2013 on ClinicalTrials.gov (NCT00527423_2012-2013)	
	17	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00637377 "Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)" 667 pages, Latest version submitted December 16, 2011 on ClinicalTrials.gov (NCT00637377_2008-2011)	
	18	Information from ClinicalTrials.gov archive History of Changes for Study: NCT00637377 "Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)" 289 pages, Latest version submitted November 28, 2014 on ClinicalTrials.gov (NCT00637377_2012-2014)	

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	19	Information from 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)" 135 pages, Latest version submitted May 2, 2011 on ClinicalTrials.gov (NCT00789477_2008-2011)	
	20	Information from 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)" 53 pages, Latest version submitted August 28, 2014 on ClinicalTrials.gov (NCT00789477_2013-2014)	
	21	Information from 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)" 98 pages, Latest version submitted May 9, 2011 on ClinicalTrials.gov (NCT00943072_2009-2011)	
	22	Information from 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)" 64 pages, Latest version submitted April 16, 2013 on ClinicalTrials.gov (NCT00943072_2012-2013)	
	23	MAJOR et al., "DA VINCI: DME and VEGF Trap-Eye: Investigation of Clinical Impact: Phase 2 Study in Patients with Diabetic Macular Edema (DME)" ARVO Annual Meeting Abstract (April 2010)	
	24	NGUYEN et al., "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" ARVO Annual Meeting Abstract (April 2011)	
	25	NGUYEN et al., "Results of a Phase I, Dose-Escalation, Safety, Tolerability, and Bioactivity Study of Intravitreous VEGF Trap in Patients with Neovascular Age-Related Macular Degeneration" ARVO Annual Meeting Abstract (May 2006)	
	26	Regeneron SEC Form 10-K (February 27, 2008)	
	27	Regeneron SEC Form 10-K (February 26, 2009)	
	28	Regeneron SEC Form 10-K (February 17, 2011)	
	29	Regeneron SEC Form 10-Q (May 8, 2006)	
	30	Regeneron SEC Form 10-Q (August 8, 2006)	
	31	Regeneron SEC Form 10-Q (November 6, 2006)	
	32	Regeneron SEC Form 10-Q (May 4, 2007)	
	33	Regeneron SEC Form 10-Q (August 3, 2007)	
	34	Regeneron SEC Form 10-Q (April 30, 2009)	
	35	Regeneron SEC Form 10-Q (November 3, 2009)	
	36	Regeneron SEC Form 10-Q (April 29, 2010)	
	37	Regeneron SEC Form 10-Q (July 28, 2010)	
	38	Regeneron SEC Form 10-Q (October 28, 2010)	
	39	Regeneron SEC Form 10-Q (May 3, 2011)	
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	42	Regeneron SEC Form 8-K Exhibit: "Press Release of Regeneron Pharmaceuticals, Inc. dated May 1, 2006" (May 2, 2006)	
	43	Regeneron SEC Form 8-K Exhibit: "Press Release of Regeneron Pharmaceuticals, Inc. dated May 3, 2006" (May 5, 2006)	
	44	Regeneron SEC Form 8-K Exhibit: "Slides presented at the Company's 2006 Annual Meeting of Shareholders held on June 9, 2006" (June 9, 2006)	
	45	Regeneron SEC Form 8-K Exhibit: "Press Release dated May 2, 2007" (May 3, 2007)	
	46	Regeneron SEC Form 8-K Exhibit: "Overheads for presentation at Regeneron's Annual Meeting of Shareholders to be held on June 8, 2007" (June 8, 2007)	
	47	Regeneron SEC Form 8-K Exhibit: "Press Release dated October 1, 2007" (October 1, 2007)	
	48	Regeneron SEC Form 8-K Exhibit: "Press Release dated November 6, 2007" (November 6, 2007)	
	49	Regeneron SEC Form 8-K Exhibit: "Press Release dated May 1, 2008" (May 2, 2008)	
	50	Regeneron SEC Form 8-K Exhibit: "Press Release dated November 4, 2008" (November 4, 2008)	
	51	Regeneron SEC Form 8-K Exhibit: "99(a) Slides that Regeneron Pharmaceuticals, Inc. intends to use in conjunction with meetings with investors at the J.P. Morgan 27th Annual Healthcare Conference in San Francisco on January 12-15, 2009." (January 9, 2009)	
	52	Regeneron SEC Form 8-K Exhibit: "Press Release dated April 30, 2009" (May 1, 2009)	
	53	Regeneron SEC Form 8-K Exhibit: "Press Release dated November 3, 2009." (November 4, 2009)	
	54	Regeneron SEC Form 8-K Exhibit: "Press Release Reporting Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME) dated December 20, 2010." (December 20, 2010)	
	55	Regeneron SEC Form 8-K Exhibit: "Press Release dated February 17, 2011" (February 18, 2011)	
	56	Regeneron SEC Form 8-K Exhibit: "Press Release Reporting Positive Results for VEGF Trap-Eye in Second Phase 3 Study in Central Retinal Vein Occlusion, dated April 27, 2011" (April 27, 2011)	
	57	Regeneron SEC Form 8-K Exhibit: "Press Release dated May 3, 2011." (May 3, 2011)	
	58	Regeneron SEC Form 8-K Exhibit: "Press Release, dated June 17, 2011, Announcing that EYLEA™ (aflibercept ophthalmic solution) Received Unanimous Recommendation for Approval for Treatment of Wet AMD from FDA Advisory Committee." (June 21, 2011)	
	59	Regeneron SEC Form 8-K Exhibit: "Presentation entitled VEGF Trap-Eye in CRVO: 1-year Results of the Phase 3 COPERNICUS Study" (August 22, 2011)	
	60	Regeneron SEC Form 8-K Exhibit: "Press Release Announcing FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration, dated November 18, 2011" (November 21, 2011)	

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	62	Regeneron Pharmaceuticals Inc., "An Exploratory Study of the Safety, Tolerability and Biological Effect of a Single Intravitreal Administration of VEGF Trap in Patients with Diabetic Macular Edema" poster presented at the 2007 Association for Research in Vision and Ophthalmology meeting in Ft. Lauderdale, Florida (May 2007)	
	63	Regeneron Pharmaceuticals Inc., "Optical Coherence Tomography Outcomes of a Phase 1, Dose-Escalation, Safety, Tolerability, and Bioactivity Study of Intravitreal VEGF Trap in Patients with Neovascular Age-Related Macular Degeneration: The CLEAR-IT 1 Study" poster presented at the 2007 Association for Research in Vision and Ophthalmology meeting in Ft. Lauderdale, Florida (May 2007)	
	64	Regeneron Pharmaceuticals Inc., " VIEW 1 Vascular Endothelial Growth Factor (VEGF) Trap-Eye 1-Year Results: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) " presented at Bascom Palmer Eye Institute's Angiogenesis, Exudation and Degeneration 2011 meeting in Miami, Florida (February 12, 2011)	
	65	Regeneron Pharmaceuticals Inc., " VIEW 2 Vascular Endothelial Growth Factor (VEGF) Trap-Eye 1-Year Results: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) " presented at Bascom Palmer Eye Institute's Angiogenesis, Exudation and Degeneration 2011 meeting in Miami, Florida (February 12, 2011)	
	66	Regeneron Pharmaceuticals Inc., "VEGF Trap-Eye CLEAR-IT 2 Final Primary Endpoint Results" presented at the 2007 Retina Society Conference in Boston, Massachusetts (September 30, 2007)	
	67	Regeneron 2008 Annual Report	
	68	Regeneron 2009 Annual Report and 10-K	
	69	Regeneron 2010 Annual Report and 10-K	
	70	RUDGE et al. "Clinical Development of VEGF Trap" In: Figg W.D., Folkman J. (eds) Angiogenesis (2008)	
	71	SCHMIDT-ERFURTH et al. "Primary Results of an International Phase III Study Using Intravitreal VEGF Trap-Eye Compared to Ranibizumab in Patients with Wet AMD (VIEW 2)" ARVO Annual Meeting Abstract (April 2011)	
	72	SLAKTER et al., "Influence of Baseline Angiographic Classification on Outcomes in the CLEAR-IT 2 Phase 2 Study of Intravitreal VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration" ARVO Annual Meeting Abstract (April 2010)	
	73	SLAKTER et al., "A Phase 2, Randomized, Controlled Dose-and Interval-Ranging Study of Intravitreal VEGF Trap-Eye in Patients with Neovascular Age-Related Macular Degeneration: Optical Coherence Tomography (OCT) and Fluorescein Angiography (FA) Outcomes at 1 Year" ARVO Annual Meeting Abstract (April 2009)	

Examiner Signature	/JON M LOCKARD/	Date Considered	11/02/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.L/

Doc Code: IFEE PTOL/85B-EFS

Document Description: Issue Fee Payment (PTO-85B)

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
16397267	29-Apr-2019	George YANCOPOULOS	REGN-008CIPCON5	8135

TITLE OF INVENTION :

USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Regular Undiscounted	Utility under 35 USC 111(a)	1647	134100	JON LOCKARD

Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
$1200	$0	$1200	12-Feb-2021	$0

1.Change of Correspondence Address and/or Indication Of Fee Address (37 CFR 1.33 & 1.363)

Current Correspondence Address:	Current Indicated Fee Address :
96387 Regeneron - Bozicevic, Field & Francis 201 REDWOOD SHORES PARKWAY SUITE 200 REDWOOD CITY CA 94065 UNITED STATES 650 327 3400 docket@bozpat.com	
☐ Change of correspondence address requested, system generated AIA/122-EFS form attached	☐ Fee Address indication requested, system generated SB/47-EFS form attached

2.Entity Status

Change in Entity Status

○ Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.
Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.

○ Applicant asserting small entity status. See 37 CFR 1.27.
Note: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

◉ Applicant changing to regular undiscounted fee status.
Note: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 5613

Samsung Bioepis Exhibit 1017, pg. 5613

Doc Code: IFEE PTOL/85B-EFS

Document Description: Issue Fee Payment (PTO-85B)

3.The Following Fee(s) Are Submitted:

☒ Issue Fee	☐ I authorize USPTO to apply my previously paid issue fee to the current fees due
☐ Publication Fee	☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____
☐ Advance Order - # of copies _____	☒ If **in addition to** the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number 500815 . The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed

NOTE: If no name is listed, no name will be printed
For printing on the patent front page, list to be displayed as entered

1. THOMAS TRIOLO
2. KARL BOZICEVIC
3.

5.Assignee Name(s) and Residence Data To Be Printed

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

Name	City	State	Country	Category
REGENERON PHARMACEUTICALS, INC.	Tarrytown	NEW YORK	united states	corporation

6.Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application. I also certify that this Fee(s) Transmittal form is being transmitted to the USPTO via EFS-WEB on the date indicated below.

Signature	/Karl Bozicevic/	**Date**	12-04-2020
Name	Karl Bozicevic	**Registration Number**	28807

WEB IFEE 1.0

Electronic Patent Application Fee Transmittal

Application Number:	16397267
Filing Date:	29-Apr-2019
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Filer:	Karl Bozicevic/Kimberly Zuehlke
Attorney Docket Number:	REGN-008CIPCON5

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1200**

Electronic Acknowledgement Receipt	
EFS ID:	41297138
Application Number:	16397267
International Application Number:	
Confirmation Number:	8135
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Customer Number:	96387
Filer:	Karl Bozicevic/Kimberly Zuehlke
Filer Authorized By:	Karl Bozicevic
Attorney Docket Number:	REGN-008CIPCON5
Receipt Date:	04-DEC-2020
Filing Date:	29-APR-2019
Time Stamp:	14:43:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1200
RAM confirmation Number	E2020B4E43225530
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	46438 06ccfac4d1ca8cad9726486470708799fe4a27b	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32494 00b3b86e03732c6619e117d707d7a62bf5f64bd9	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	78932		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/397,267	01/12/2021	10888601	REGN-008CIPCON5	8135

96387 7590 12/22/2020

Regeneron - Bozicevic, Field & Francis
201 REDWOOD SHORES PARKWAY
SUITE 200
REDWOOD CITY, CA 94065

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

George D. YANCOPOULOS, Yorktown Heights, NY;
REGENERON PHARMACEUTICALS, INC., Tarrytown, NY

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