

Q2 2012 Earnings Call

Company Participants

- George Yancopoulos, EVP, Chief Scientific Officer, President
- Leonard Schleifer, President, CEO
- Michael Aberman, VP Strategy & IR
- Murray Goldberg, SVP Finance & Administration, CFO
- Robert Terifay, SVP Commercial

Other Participants

- Biren Amin, Analyst
- Chris Raymond, Analyst
- Jeff Meachum, Analyst
- Jim Birchenough, Analyst
- Joseph Schwartz, Analyst
- Mani Mohindru, Analyst
- Phil Nadeau, Analyst
- Steve Byrne, Analyst
- Ted Tenthoff, Analyst
- Terence Flynn, Analyst
- Unidentified Participant
- Yaron Werber, Analyst

Presentation

Operator

Good morning, ladies and gentlemen, and welcome to the Regeneron Pharmaceuticals conference call to discuss the Second Quarter 2012 financial results. My name is Kevin and I will be your coordinator today. At this time all participants are in a listen-only mode. We will conduct a question-and-answer session towards the end of this conference call. As a reminder, this conference is being recorded for replay purposes. I would now like to turn the call over to Dr. Michael Aberman, Vice President of Strategy, Investor Relations for Regeneron. Please proceed, Dr. Aberman.

Michael Aberman {BIO 6989908 <GO>}

Thank you, operator and good morning and welcome to Regeneron Pharmaceuticals Second Quarter 2012 conference call. An archive of this webcast will be available on our website under events and presentation for 30 days. Joining me on the call today is Dr.

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Leonard Schleifer, the Founder, President and Chief Executive Officer, George Yancopoulos Executive Vice President, Chief scientific Officer and President of Regeneron Research. Murray Goldberg, Chief Financial Officer, and Robert Terifay, Senior Vice President, Commercial. After our prepared remarks we will open the call for Q&A.

I would also like to remind you that remarks made on this call that are not historical in nature may be forward-looking statements about Regeneron and are subject to a number of risks and uncertainties. Actual events and our actual results may differ materially. Such remarks may include but are not limited to those related to Regeneron and its products and businesses, sales forecasts, financial forecasts, development programs, collaborations finances, regulatory matters, intellectual property and competition all of which involve a number of risks and uncertainties.

A more complete description of these and other material risks can be found in Regeneron's filing with the United States Securities and Exchange Commission or SEC, including its form 10-K for the year ended December 31, 2011, and form 10Q for the quarter ended June 30, 2012 which we filed this morning. 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. GAAP and non-GAAP measures will be discussed on today's call.

Information regarding our use of non-GAAP financial measures and a reconciliation of these measures to GAAP are available in our financial results press release which can be accessed on our website. Once our call concludes, myself and the IR team will be available to answer further questions. With, that let me turn the call over to our President and Chief Executive Officer, Dr. LenSchleifer.

Leonard Schleifer {BIO 1463677 <GO>}

Thanks Michael. Good morning, to everyone. In terms of the agenda for today, following my brief introductory remarks George Yancopoulos, Chief Scientific Officer will provide an update on our pipeline, Bob Terifay, Senior Vice President of Commercial will then provide an update on the EYLEA launch, and Murray Goldberg our Chief Financial Officer, will wrap up with financial highlights before I offer some concluding remarks and we open the call for questions and answers.

Today we are happy to report a very successful quarter as our team continues to execute on the ongoing launch of EYLEA, also known as intravitreal aflibercept injection. We saw a strong quarter-over-quarter growth with U.S. net sales of \$194 million representing a 57% increase over the last quarter.

Given the trajectory of the launch to date tempered by the potential for less frequent dosing as doctors increase the interval between injections of EYLEA, we are increasing our full year U.S. EYLEA net sales forecast to between \$700 million and \$750 million from a prior \$500 million to \$550 million. If we achieve this new forecast, EYLEA will become one of the best drug launches in the history of the biotechnology industry.

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In a few minutes, Bob Terifay will go into some more details on the launch. Importantly the strong EYLEA sales growth translated into even stronger earnings growth where we saw non-GAAP net income rise more than two-and-a-half fold from \$40 million last quarter to slightly over \$100 million in the Second Quarter of 2012, which translated into non-GAAP fully diluted earnings per share of \$0.90.

Obviously, we are pleased by both the performance of EYLEA, as well as its ability to fuel the Company's earnings. The ability to translate sales growth into strong earnings growth while still investing heavily in our robust and internally discovered pipeline that includes ten antibodies in addition to our three TRAPs highlights our relatively unique business model.

Our PDUFA date in the U.S. for SBLA for EYLEA for CRVO is September 23rd, and an approval would further expand the EYLEA opportunity. As a reminder, the strong commercial results for EYLEA only reflect the launch of EYLEA in the U.S.

Outside the United States, our partner, Bayer HealthCare has already received marketing approval in two countries, Australia and Columbia, and we are waiting regulatory decisions in the EU, Japan and other countries. We expect the global launch to start toward the end of the year. To that end, during the Second Quarter Bayer HealthCare consummated an agreement with Santen, the market-leading ophthalmology company in Japan to co-promote EYLEA in Japan. We think this will accelerate the launch and further bolster the opportunity in Japan.

Beyond EYLEA we await FDA action on our application to market ZALTRAP or aflibercept injection for intravenous infusion in combination with a FOLFIRI chemotherapy regimen for patients with metastatic colorectal cancer that was previously treated with an oxali-platinum-containing regimen. We are also advancing our robust pipeline including our late stage phase three programs Sarilumab targeting the IL-6 receptor, and Regeneron727 targeting PCSK9.

Let me highlight PCSK9 briefly because that is a program that is generating a lot of excitement not only within Regeneron, but within the clinical community and pharmaceutical industry. Surely we have a lot of competitors, but we believe we are in the lead and are committed to trying to stay in front. We and our partner, Sanofi, just announced that we have initiated our broad 22,000 patient phase three program known as ODYSSEY.

In addition, Sanofi has formed a dedicated development unit for the program emphasizing their commitment to this important investigational agent. With that, let me turn to our Chief Scientific Officer George Yancopoulos to highlight some important achievements in our pipeline during the Second Quarter.

George Yancopoulos {BIO 1463723 <GO>}

Thanks, Len. Our clinical and regulatory teams continue to be extremely busy with three BLAs currently under review at the FDA and regulatory decisions expected in the next few

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months. First, ZALTRAP for the treatment of previously treated metastatic colorectal cancer has a PDUFA date of August 4. We are only a few days away from the PDUFA date and are hopeful for a timely approval. While we do not have a substantial development -- while we do have a substantial development cost repayment obligation to Sanofi that will limit our recognition of any profits for ZALTRAP for some time, ZALTRAP potentially represents our first commercial foray into oncology.

As a reminder, we have been pioneers in the field of angiogenesis, so it's particularly satisfying to be able to look forward to making ZALTRAP or VEGF trap available to patients. Moreover, in our clinical pipeline are two antibodies -- two novel angiogenesis targets, angiopoietin-2 and DLL4 that have the potential to improve upon VEGF inhibition alone.

Second, we have previously submitted our SBLA for EYLEA for the treatment of central retinal vein occlusion or CRVO which has a September 23rd PDUFA date. We also will be following the upcoming FDA Advisory Committee meeting on anti-VEGF therapy for DME very closely as both of our phase three trials for EYLEA and DME, VISTA-DME and VIVID-DME, are fully enrolled.

As a reminder, outside the U.S., approval in DME can come within one year of efficacy data while in the U.S. current FDA guidance requires two years. We have also started enrollment in a phase three trial for branch retinal vein occlusion or BRVO.

And finally, we are less optimistic for the supplemental BLA for ARCALYST or rilonacept, for the prevention of gout flares in patients initiating uric acid-lowering therapies, which has a PDUFA date of July 30th. As most of you know arthritis advisory committee convened by the FDA voted against the approval of ARCALYST in this indication. While the advisory committee's decision is not binding on the FDA, we have low expectations for an approval in this indication at this time and are working to determine the appropriate path forward. We continue to market ARCALYST for the treatment of CAPS.

Turning to our antibody pipeline, we now have advanced two antibodies from a broad antibody collaboration with Sanofi into phase three testing. Regeneron727 for cholesterol lowering and Sarilumab for rheumatoid arthritis. As Len mentioned, Regeneron727 is our cholesterol-lowering PCSK9 antibody which continues to garner a great amount of interest in the clinical community as potential first in class new treatment for high cholesterol.

During the Second Quarter, we presented positive phase two data at a late-breaking session of the European Atherosclerosis Society and also announced publication of these data in the Lancet. Our phase two program as a whole showed Regeneron727 can significantly reduce LDL cholesterol, also known as the bad cholesterol, up to more than 70% in a variety of settings, including in patients who are not at goal on maximum doses of other background lipid-lowering therapies such as high dose statins. In the phase two program, injection site reactions were the most common adverse events and rare cases of hypersensitivity reaction were also reported.

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With that in mind, Sanofi and Regeneron announced just a few days ago at the launch of the 22,000 patient global phase three program for PCSK9 called ODYSSEY which will consist of more than 10 clinical trials to evaluate the safety and efficacy of Regeneron727 in a broad range of patients. This will be the first phase three program evaluating a PCSK9-targeted therapy. As described in our press release last Friday, the phase three program will test the efficacy and safety of Regeneron727 in a variety of patients with high unmet medical needs such as patients with familial hypercholesterolemia, and those with elevated cardiovascular risk who cannot reach their LDL cholesterol goals with current standard lipid-lowering therapies.

The market opportunity is large with 10 million patients in the U.S. alone who are not at goal despite being on existing therapies. LDL cholesterol lowering remains the primary objective for the management of hypercholesterolemia and this has been supported by a large body of data.

Based on our end-of-phase-two discussions with the U.S. and European regulatory authorities during the Second Quarter, we expect LDL cholesterol to be the primary end point for our regulatory filings and the basis for our initial approval. Obviously this depends on an acceptable safety profile in the phase three studies and no sea change in the regulatory view around LDL as a valid surrogate endpoint. The ODYSSEY program includes a large cardiovascular outcomes trial that will enroll approximately 18,000 patients and will start later this year. We expect this trial to be well under way at the time of the BLA filing for Regeneron727 but we do not anticipate that the final results of that trial will be a prerequisite for filing.

Sarilumab our subcutaneous IL-6 receptor antibody for rheumatoid arthritis continues to enroll patients in the phase three mobility trial. There's growing excitement about the IL-6 class of drugs given data recently presented for Actemra or tocilizumab, an approved IL-6 receptor antibody in a head-to-head study VS Humira or adalimumab, the leading anti-TNF for the treatment of rheumatoid arthritis. There are 2.7 million patients treated worldwide for RA each year. We look forward to initiating additional Sarilumab phase three studies with our partner Sanofi later this year.

Another positive development for our pipeline, as we mentioned on our last call, was a FDA advisory committee's unanimous vote in favor of a role for the ongoing development of anti nerve-growth factor, antiNGF agents for pain associated with osteoarthritis. Pain represents an enormous unmet need and it is estimated that 25 million patients worldwide suffer from moderate to severe osteoarthritis and about 4 million of them are intolerant to or poorly responsive to existing therapies.

We also can report that we have had discussions with the FDA and look forward to updating you on the clinical development plans for our antiNGF antibody, Regeneron475 once they are finalized. As a reminder we have full sole rights to Regeneron475. I would now like to turn the call over to Bob Terifay to provide an update on the EYLEA launch

Robert Terifay {BIO 4342122 <GO>}

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Thank you, George. Our commercial organization is thrilled with the reception that EYLEA received in the wet AMD market, as evidenced by the 57% growth in our net product sales for the Second Quarter to \$194 million. We believe that there are several factors that have contributed to the continued strength of our launch. Our market research suggests that EYLEA enjoys an increasing level of market awareness.

This market awareness, combined with the facts that EYLEA offers clinically equivalent efficacy to monthly Lucentis or ranibizumab, with the convenience of less than monthly dosing, and secondly, that many doctors continue to switch patients from Lucentis, and off-label Avastin or bevacizumab, to EYLEA has allowed us to establish what we believe is a very strong foot hold in the wet AMD market. Based on qualitative market research surveys that we conducted towards the ends of June of 2012, EYLEA has now been used in approximately 90% of all accounts where Lucentis has been used up from the 70% that was reported in the First Quarter. Clearly, this indicates that some of our growth this past quarter came from an increase in the number of accounts that are using EYLEA.

In terms of penetration and/or market share within these accounts, our market research suggests that EYLEA has now captured approximately 14% of the overall wet AMD, anti-VEGF market by volume. This is an increase from the 10% market share that we estimated on our First Quarter earnings call. Based on qualitative market research survey results we estimate that at the time of our survey, patients continuing on EYLEA represent approximately 40% of our sales. 35% comes from wet AMD patients new to anti-VEGF therapy and the remaining 25% come from patients switching from other anti-VEGF therapies.

In terms of our switchers, our new market research indicates that about half of the switches are coming from Avastin. Both efficacy and the convenience of less than monthly dosing are cited as the key drivers for starting a naive patient and switching a patient to EYLEA from either Avastin or Lucentis. In order to better understand the dynamics of this market, including the reason why patients switch to EYLEA, we look forward to the upcoming American Society of Retinal Surgeons meeting in Las Vegas in August where there will be a special session devoted to independently prepared presentations from several retinal practices around the country reporting on their initial experiences with EYLEA in this specific patient population of switches.

There are several factors that influence a successful drug launch. One of the key drivers for a buy-and-build product such as EYLEA is successful reimbursement. To this end, we've made an effort to streamline and facilitate the reimbursement process. We continue to see successful reimbursement from all of the regional Medicare carriers, secondary and supplemental insurers and commercial and private pairs. All targeted commercial pairs are now covering EYLEA with several commercial pairs now having published coverage policies. We have also seen broad adoption by hospital formularies.

We expect to receive our permanent J-code in January 2013 and I anticipate this will further streamline the automated EYLEA claims process and provide an additional degree of comfort to those accounts who might have been sitting on the sidelines awaiting confirmation that reimbursement would not be an issue for them. In the meantime, on the

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first of July, our temporary Q-code for EYLEA went into effect. A Q-code is a temporary but specific code for EYLEA, that result in automated reimbursement.

To ensure as seamless transition as possible to the Q-code from the miscellaneous J-code, we have in place a team of regional business managers who are working closely with physician office managers to facilitate reimbursement. We've already seen that certain Medicare carriers who had slow processing turn around times for claims submitted using a miscellaneous J-code have already processed claims more quickly using the EYLEA-specific Q-code that only became available on July 1st. While these sales metrics are reassuring and we expect continued growth in EYLEA usage, we are mindful that it is unrealistic to expect this pace of growth to continue for the remaining two quarters of the year.

With more and more of our sales coming from patients continuing on EYLEA treatment, we do expect an impact from patients moving from the monthly loading dose phase to less monthly dosing regimens, including the every other month dosing regimen recommended in the EYLEA prescribing information. We also expect to see a decline in the number of patients available in each practice to be switched to EYLEA from other VEGF inhibitors. In addition, since we've now penetrated about 90% of the accounts that are known to have used Lucentis, we expect a slowdown in the rate of new account growth. On the other hand, as doctors gain experience with EYLEA in both naive patients and switches, we also expect further share gains in both of these segments. Bottom line is that we expect continued growth for EYLEA but at a slower rate in the second half of the year.

As a result, we are increasing our full year EYLEA U.S. sales -- net sales forecast to \$700 million to \$750 million. If our new forecast is achieved, it would make EYLEA one of the top bio-pharmaceutical launches of all times. Turning outside the United States, which we expect to be a significant contributor to EYLEA growth in 2013 and beyond, EYLEA was recently approved for the treatment of wet AMD in both Australia and Columbia.

In addition, our partner, Bayer HealthCare has filed for the wet AMD indication in Europe and Japan and we anticipate approval and launches on a country-by-country basis in Europe and Japan starting at the ends of this year and continuing throughout 2013. Bayer has also announced that they plan to submit a filing of the CRVO indication shortly following Ex-US wet AMD approvals. As Len mentioned earlier, Bayer entered into a copromotion agreement with Santen in Japan.

We and Bayer expect this agreement will allow EYLEA to have broader and faster reach into the Japanese ophthalmology community. As part of this agreement, we have converted our profit split in Japan into a tiered royalty of between 33.5% and 40% on EYLEA net sales in Japan. While the EYLEA launch is only just beginning, its initial early success increases our confidence that EYLEA can continue not only to deliver near term growth through the continued launch in wet AMD in the United States and shortly outside the United States, but also long-term revenue growth through expansion into new indications globally. Now let me turn it back to Len

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Leonard Schleifer {BIO 1463677 <GO>}

Thanks, Bob. Before moving to Murray to review financial results, let me take a moment to address the competitive landscape in wet AMD and our long-term vision for Regeneron in ophthalmology. EYLEA represents the culmination of years of internal research and development for Regeneron in the field of angiogenesis. Where we were early pioneers and made seminal discoveries.

We were not the first anti-VEGF to reach the market for the treatment of eye diseases. In fact EYLEA is the third approved anti-VEGF product after Macugen and then Lucentis. However, our goal is for EYLEA to become the global market leader.

Given this history, we are very aware that research and innovation will not stop at EYLEA and patients and physicians will be looking for the next innovation in treatment of wet AMD. Thus we continue to invest in research to not only find ways to improve EYLEA but also to find novel approaches and targets to treat wet AMD and other eye diseases. For example, in the Sanofi collaboration we are developing an angiopoietin-2 antibody for cancer that's based on preclinical data may also have potential to be developed for treatment for diseases of the eye. Over the last several years our scientists have also been exploring the role of platelet derived growth factor or PDGF, in angiogenesis. We currently have a high-affinity PDGF antibody in preclinical development that we expect to be in the clinic in 2013.

As reminder, Sanofi has certain option rights to our antibodies. It is important to note that a blocking PGDF does provide an added benefit over VEGF inhibition alone in diseases of the eye. We believe it is important to try and develop a potent inhibitor, combine it with a best VEGF blocker, and attempt to development as a single coformulated injection if possible. Importantly, we know first hand how long and difficult the road to the market can be as it took approximately four years from the first patient enrolled in our phase three EYLEA program to our initial launch in the U.S.

As such, from what we see in the competitive landscape now, we don't expect any new entrants to the wet AMD market before the 2017, 2018 time frame. That said, we are committed to investing to maintain our leadership position through continued innovation. With, that I would now like to turn the call over to Murray who will review our Second Quarter financial results.

Murray Goldberg {BIO 1463711 <GO>}

Thank you, Len, and good morning everyone. I'm very pleased to discuss our financial results for the Second Quarter of 2012, which brought Regeneron to a new milestone with over \$100 million of non-GAAP profit in a quarter. Total revenues in the Second Quarter were \$304 million. This included \$194 million of EYLEA net sales and about \$6 million of ARCALYST net sales.

The gross-to-net adjustment for EYLEA sales was similar to last quarter at approximately 7.5%. For EYLEA, this quarter's distributor inventory remained consistent with prior

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quarters at about one to two weeks of inventory on hand. As a result, EYLEA net sales included a modest increase in distributor inventory of about \$10 million.

Collaboration revenue was \$98 million in the Second Quarter. This primarily included Sanofi's reimbursement to us of \$92 million for antibody and ZALTRAP R&D expenses that we incurred offset by approximately \$8 million in pre-commercialization expenses for ZALTRAP that Sanofi incurred and that we reimbursed them for. Our reimbursement to Sanofi is accounted for as contra revenue.

Looking forward in 2012, this line would include growing pre-commercialization expenses for ZALTRAP in preparation for potential launch in a variety of countries at the end of this year and next year. Our share of these pre-commercialization expenses would potentially be at least partially offset by the approval milestone of \$50 million. If we were to receive regulatory approval from the FDA.

Bayer HealthCare collaboration revenue was about \$9 million in the Second Quarter and primarily represents Bayer's cost sharing of some of the EYLEA development expenses that we incurred. As EYLEA launches globally, Bayer HealthCare collaboration revenue will also include our share of the pre-commercialization expenses and our share of the profits and losses from commercialization outside the United States, as well as potential approval and sales milestones from Bayer.

Costs of goods sold in the Second Quarter was \$22 million or 10.9% of net product sales overall and about 10.5% for EYLEA. This includes royalty expense in connection with our Genentech license agreement relating to ophthalmic sales of EYLEA in the U.S. It also includes inventory write-offs and reserves of approximately \$6.5 million that increased costs of goods sold for the quarter. Non-GAAP R&D expense was \$136 million for the Second Quarter this year, about the same as in the Second Quarter last year.

If we back out R&D reimbursements from our partners during the quarter from our R&D line, our net non-GAAP unreimbursed R&D expense for the Second Quarter was \$37 million compared to \$34 million in the First Quarter. We anticipate that this net R&D expense will continue to trend upward through the remainder of 2012 and would increase much faster if antibodies outside the Sanofi collaboration such as our NGF antibody Regeneron475 move into advanced stage clinical trials.

Non-GAAP SG&A expenses were \$40 million for the Second Quarter this year compared to \$20 million in the Second Quarter last year. The increase in SG&A expense versus last year is primarily due to the fully-burdened cost of the EYLEA field force and other EYLEA commercialization-related expenses. In April, we provided full-year non-GAAP SG&A expense guidance of \$180 to \$210 million. In the event that the FDA does not grant approval for ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering therapy, which is what we currently expect, our non-GAAP SG&A would be in the lower ends of that range.

As a reminder, non-GAAP R&D and non-GAAP SG&A expenses include -- exclude non-cash share-based compensation expense. Turning to the bottom line, we reported non-

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GAAP net income of \$102 million for the Second Quarter, which is equivalent to non-GAAP fully diluted EPS of \$0.90. Non-GAAP net income excludes non-cash share-based compensation expense and non-cash interest expense related to do our convertible senior notes. On a GAAP basis, we had net income of \$77 million or \$0.70 per diluted share.

For the full year, we expect to be profitable on both the GAAP and non-GAAP basis. As you will note, despite turning profitable for the quarter, we have not provided for a tax liability as we have released a portion of our full valuation allowance against our large balance of net operating loss carry forwards and other tax credits. When we transition into showing consistent profit, we will provide more guidance on the accounting treatment of these NOLs and tax credits.

On a cash basis we do not anticipate that we will have a cash tax liability for at least several years. Our non-GAAP fully diluted shares outstanding in the Second Quarter were approximately 115 million shares and include about 16 million shares attributable to stock options, restricted stock and warrants accounted for using the treasury method and about 5 million shares associated with our convertible notes accounted for using the if converted method. At June 30, we have \$597 million of cash and marketable securities compared to \$811 million in year-end 2011. The decrease is primarily attributable to the extended payment terms on EYLEA sales.

As you'll recall, in connection with the launch of EYLEA, we offered our distributors extensive payment terms and they, in turn offered physicians extended payment terms of up to six months to provide ample time for physicians to receive reimbursement from Medicare and other insurance providers for their EYLEA usage. At June 30, our trade receivables totaled about \$350 million, almost all related to do EYLEA sales. Now that we are in the ninth month of launch those receivables have begun to be paid down though the account balance continues to increase because of our growing EYLEA sales. For the second half of this year, we currently expect to be cash positive. Thank you, and with that I'll turn the call back to Len

Leonard Schleifer {BIO 1463677 <GO>}

Thanks, Murray, Bob, George. This was truly another great quarter for Regeneron. Let me conclude today's call by making a few comments about the bigger picture for Regeneron. This quarter marks another step forward towards our goal of becoming a leading biopharmaceutical company as well as a long-term growth company for investors both in terms of revenue and earnings.

At a time when many large pharmaceutical companies are cutting back their research, shutting down major research centers and looking externally for innovative science and product opportunities, we are investing in research, investing in our people and expanding our manufacturing capacity. We are also seeing our past investments and collaborations bear fruit with a robust pipeline that has multiple BLAs under review at the FDA, 10 antibodies in the clinic, two of which are in phase three, and addition to antibodies expected to enter the clinic by the end of this year and each year thereafter. All of these products and product candidates were invented at Regeneron by Regeneron

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scientists and Regeneron laboratories led by George Yancopoulos our Chief Scientific Officer and my partner since the founding of the company over 20 years ago.

This is an exciting time for Regeneron and I want to again thank our dedicated employees who have helped us achieve our goals, the many investors who stuck with us for a long time patiently waiting to see us reach this point, and all the patients, their family members and physicians who participated in our clinical trials and will continue to contribute to our future. With that, let me turn the call back over to Michael for questions.

Michael Aberman {BIO 6989908 <GO>}

Thank you, Len that concludes our prepared remarks. We would now like to open the call for Q&A. As we'd like to give as many people a chance to ask questions as possible we do request that you limit yourself to one question. The IR team will be available in our office after the call for follow-up questions. Thank you, and operator, if you could please open the call for questions.

Questions And Answers

Operator

(Operator Instructions) Our first question comes from Steve Byrne with Bank of America

Q - Steve Byrne {BIO 7019262 <GO>}

Hi. I wanted to do drill into your survey results a little bit more Bob. You mentioned 14% share of wet AMD by volume. I assume that's by patients. I was wondering if out of that 35% that is for patients naive to anti-VEGF can you comment on what your share is of that pool of patients? What portion of those are being treated with EYLEA relative to alternative VEGF?

A - Robert Terifay {BIO 4342122 <GO>}

Steve, to clarify, the way we have calculated our share is based upon eyes. So the equivalent of that would be a vial of drug. In terms of market share, I just need to remind you these were market shares projected by physicians in a qualitative survey in June. It is not based on a chart audit or anything. So it's physician perceptions. What they've reported is that the market share overall, as well as the new patient market share are fairly similar at about 14%. But again, it's qualitative. It's not a chart audit.

Q - Steve Byrne {BIO 7019262 <GO>}

and one geographic region I didn't hear mentioned about was Brazil. Is Bayer looking into the opportunity in that country?

A - Robert Terifay {BIO 4342122 <GO>}

Bayer is looking globally. We haven't discussed filing strategies outside of EU and Japan as of yet

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A - Leonard Schleifer {BIO 1463677 <GO>}

But you can be sure that over time they will be in every significant market

A - Michael Aberman {BIO 6989908 <GO>}

Great. Next question, please.

Operator

Our next question comes from Robyn Karnauskas of Deutsche Bank.

Q - Unidentified Participant

This is Alicia on behalf of Robyn. Congrats guys on a strong quarter not only in rev, but in earnings, too. Can you talk about what you learned in the U.S. that would be applicable around the doctors for the global launch of EYLEA, please

A - Leonard Schleifer {BIO 1463677 <GO>}

Yes. It's a good question. When we launched the product, of course, we were very pleased that we had what you would say is a front line label, that it's indicated for the treatment of wet AMD. But of course doctors tend to try a new drug in their most difficult patients and what we learned is that turns out to be a great strategy for us because they were very pleased with how that turned out, whether it was switches or people who weren't getting adequate response or still wet. And you'll hear more about that in the presentations I think from some of these practices and retinal meetings in August in Las Vegas. But would I say that the big -- the big thing to remember is that the EU and the rest of the world are not one market like the United States is.

So you don't know exactly how things are going to play. And this may play great in one place and in another place it may be driven solely by negotiating price and someplace else it may be just driven by how well the salespeople there are ready. I think that if there's one overriding thing we've learned and Bayer obviously has learned is that the docs like the product. So the more we can get doctors to start using the product, that becomes our best selling effort.

A - Michael Aberman {BIO 6989908 <GO>}

Next question.

Operator

Our next question comes from Chris Raymond with Robert Baird and Company

Q - Chris Raymond {BIO 4690861 <GO>}

Thanks. I'm not sure I caught all the detail you had on your developmental efforts with the anti-PDGF and the angiopoietin-2. Could you maybe just go back and give a little bit more detail? Is it your plan to develop a coformulated VEGF PEGF therapy or is this

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separate and are these two agents, PDGF and angiopoietin, are you going to pursue these in parallel? Can you maybe give a little more detail on that, please

A - Leonard Schleifer {BIO 1463677 <GO>}

Right. So I think I don't want to get into the details of our development plans and strategy because this is a competitive area. But let me just make another comment or reiterate a comment I made when we presented our opening remarks, which is that the -- the effect that's been reported to do date with a PDGF aptamer was a rather modest effect of about four letters difference between Lucentis alone. And it took two different injections to get that.

What we think the lesson there is that, A, there should be caution and if there's more questions we can drill down why there should be caution. Whether or not that is going to repeat in further studies. Second, we believe a modest effect size like that would best be delivered to the marketplace if you had a coformulated, that is you could inject once into the eye. And finally, we believe if you're going to go down this path, you want to go down the path with the best PGF blocker that you can. And the aptamer, we don't think the aptamer necessarily -- like everything else the first one may or may not necessarily be the best one Next question.

Operator

Our next question comes from Terence Flynn with Goldman Sachs

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the question and congrats on another solid quarter. I guess two, one is on the guidance front if you can just maybe give us your thoughts on where you see the greatest uncertainty in your guidance. Is it either at the front end so new patients coming on, or is it at the back end in terms of the transition from induction to maintenance dosing? And then a follow-up on the PGDF front. Can you tell us -- maybe walk us through some of the challenges of potentially including two antibodies in one injection and that's it for me. Thanks.

A - Leonard Schleifer {BIO 1463677 <GO>}

So, Bob, do you want to deal with the first question and then we can deal with George with the second one.

A - Robert Terifay {BIO 4342122 <GO>}

So we are encouraged by the survey results that indicate that we have an annuity of patients at this time, the continuing patient segment is growing. Now, remember the dosing for patients is three initial monthly doses followed by dosing every eight weeks. And we do see that in both the naive as well as the switch patients that the dosing interval is expanding beyond that four weeks after the initial loading dose period. So we'll see fewer injections in those continuing patients once they get past the initial monthly loading dose phase. However, we do see growth in new patients, which is exactly where we expect to get our revenues from. And as you would expect, there was a pool of patients

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ready for switching that is not drying up but decreasing because there was some pent up demand. So I think what you'll see is fewer injections in the continuing, decreased overall number of switches, and we'll have continued growth in the news.

A - Leonard Schleifer {BIO 1463677 <GO>}

How that equation gets solved obviously creates the uncertainty in the marketplace. George, do you want to address the issues of coformulations things like that?

A - George Yancopoulos {BIO 1463723 <GO>}

Well, the good news about trying to combine or coformulate two very similar types of biologics is that the technical or scientific hurdles are relatively minor. So there really aren't too many technical hurdles with coformulation. Of course, there will be regulatory issues and probably the most difficult issues is of course trying to get the dose and the regimens correct. Obviously, I'm sure you're all aware that's the most complicated thing about this. And it's going to take a large number of studies and attempts and so forth to figure out if there is a benefit to adding a second agent, how best to dose and interval and frequent that second type of an agent. It's going to be obviously very challenging for the whole field, including for us, to do that.

A - Leonard Schleifer {BIO 1463677 <GO>}

George, could you address the reproducibility of small effects and what we learned in that?

A - George Yancopoulos {BIO 1463723 <GO>}

Right. I guess what Leonard's referring to is in the existing phase two data with the PDGF agent, there was an apparent difference of about four letters with the double dosing giving two injections of both PDGF agent as well as an anti-VEGF agent. And obviously, these results are very interesting and exciting and they suggest that there may be a combination benefit.

On the other hand, reason for concern and caution is simply that obviously in small studies like these, the relative differences between two dose groups, even if in a particular study may appear statistically significant, are not necessarily reproduced when done again so just to give you a very simple example, two dosing groups that look in our integrated analysis to be no different, two different dosing regimens that we tried in our large phase three program where each study -- each study was more than twice as large as the reported PDGF study, in one study the relative difference between agents was four letters and then in the other study the relative difference between the two agents went two letters in the opposite direction meaning there was a six letter swing between the two studies, which, as I said, were more than -- each one was more than twice as large as those phase two-- the phase two study just reported for the PDGF agent.

So though there's reason to-be excited and we've certainly been pursuing this pathway for many years and as Len said, we think we may have a top candidate for combination-type studies, there's a lot of reason for caution about whether there really is a benefit. And

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even if there is, I think there's going to be a lot of efforts are going to be required to figure out how to optimize such a cotherapy.

A - Leonard Schleifer {BIO 1463677 <GO>}

Good. George I think we'll go on to the next question. One last point before we go on that issue is that one has to be careful also about how selected these patients were, how generalized. You don't know diabetics were treated and if there were other restrictions, so I think there's a lot of time and things to be done and learned. We're clearly yet paying close attention. Next question.

Operator

Our next question comes from Jim Birchenough with BMO Capital.

Q - Jim Birchenough {BIO 5068439 <GO>}

Hey guys, let me add my congratulations. Just on the market dynamics and trying to anticipate what proportion of patients might go from induction to maintenance dosing, right now as you look at patients on EYLEA, what proportion are getting monthly dosing versus every two month dosing and then just wondering if you can help size the treatment naive market in AMD, how many new patients do you see coming on each quarter and what's the share, if you can remind us what's the share there in the naive patients, thanks.

A - Robert Terifay {BIO 4342122 <GO>}

So I'll start with the naive patient. New patients in the wet AMD market coming in are roughly 25% to 30% of the overall market. In terms of where things are settling out on the dosing, it's really too early because we constantly, as you saw we have people who are just starting EYLEA, a fairly large group, that are even when they're switched are generally being started on a monthly loading dose, period. So we're seeing the dosing interval go out over time. I think we'll have a better sense in future earnings calls but it would be premature to give you a specific time right now.

A - Leonard Schleifer {BIO 1463677 <GO>}

Okay. Next question.

Operator

Our next question comes from Yaron Werber with Citi.

Q - Yaron Werber {BIO 19486720 <GO>}

Hey, congrats also on a great quarter. I have two questions. One, help us understand the timing in Europe for approval, it was filed back in June of last year so we're now about 14 months into it. So why wouldn't the approval be all the way at the end of the year not earlier than that? I'm talking about the approval not the actual reimbursement approval. Secondly, just as a follow-up discussion on the aptamer PDGF, if you look at the previous data again, admittedly small patient number is very interesting data. It showed, really, a

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remarkable ability to dry the eyes. I think one of the concerns is the total number of injections will go down over time as people do trim expand[ph] and they're using OCT so what are your thoughts on that?

A - Leonard Schleifer {BIO 1463677 <GO>}

So on the first one regarding the timing, I think Bayer's in charge of that and timing is what they said. You can pursue that further with them. As far as the PDGF and the drying of the eye you might recall you have to remember what it's being compared to. Lucentis has -- from our studies had less dry -- our own head-to-head studies had less dry eyes than EYLEA did. And so you're talking about eyes that are not completely dry as it is under anti-VEGF therapy. And you should also obviously remember that there's not a perfect correlation between drying of an eye and visual acuity. Next question.

Operator

Our next question comes from Biren Amin with Jefferies

Q - Biren Amin {BIO 7512048 <GO>}

Thanks for taking my questions. I wanted to maybe focus on the EYLEA DME ongoing phase three program and after reading the briefing documents released yesterday it seems FDA prefers proportion of patients gaining three lines over a three-year period. And given the (technical difficulty) is designed for visual acuity changes of two years at baseline, would you expect to revise VISTA trial design based on FDA commentary?

A - Leonard Schleifer {BIO 1463677 <GO>}

I think we've had a pretty good discussion with the FDA about our trials. And if we -- after the results of its advisory committee meeting if there's anything to do, obviously, we're going to watch it carefully. The FDA accepts both types of end points, depending -- as long as there's a certain magnitude of effect. And I believe our trial design is also a little bit different. We have an active control of laser versus they had rescue. So the trials are not exactly analogous but we feel comfortable with our trial design and we'll look at it in light of what gets discussed. Next question.

Operator

Our next question comes from Mani Mohindru with Think Equity

Q - Mani Mohindru {BIO 18658487 <GO>}

Hi. Thanks for taking my questions and my congrats to your team as well. I just want to do get a better sense of your guidance. You keep coming and surprising us. I'm trying to see what your thought processes and your updated guidance. Are you including any CRVO estimates there? And are you also taking into account some impact of the newly implemented Q-code that just went into effect earlier this month? Trying to get a sense of those two things playing into your new guidance. And on the Q-code front, I know it's very early, but have you seen any kind of impact in the few weeks that it's been on? Thanks.

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A - Leonard Schleifer {BIO 1463677 <GO>}

So two points. We never plan or project or incent based on anything but approved indications so that estimate is based solely on our view of the approved marketplace. But we can't be sure, of course. We don't always get the data to be sure what it's doing. So it's our best guess. You say we're surprising you. We get surprised as well. And so it really is our best estimate.

The other question you had is whether the Q-code has seen any effect. I think in Bob's opening remarks he's said we've already seen just since July 1 claims getting paid based on Q-codes that obviously only took a few weeks because we're only a few weeks into July to get paid. Which is a large decrease in the time to pay compared to prior to the Q-code some cases. Bob, do you want to amplify on that?

A - Robert Terifay {BIO 4342122 <GO>}

So as Len said, with regards to the CRVO, we'll just wait to see when the claim comes. But I just remind everyone, CRVO, although it's an important indication to add to our breadth of claims for EYLEA, CRVO in terms of the number of patients eligible for anti-VEGF therapy is about 10% of the wet AMD patient population. So CRVO will be a fairly small marketplace but it does expand the utility of EYLEA if we get that claim

A - Leonard Schleifer {BIO 1463677 <GO>}

Okay. Next question.

Operator

Our next question comes from Joseph Schwartz with Leerink Swann

Q - Joseph Schwartz {BIO 7261403 <GO>}

Thank you, very much and congratulations on the outstanding performance. Just to follow up on your last statement, why did you not pursue branch retinal vein occlusion when you -- when you did the central RVO studies? Thank you

A - Leonard Schleifer {BIO 1463677 <GO>}

In fact, we are pursuing it. It's just a matter of there's a lot going on. We had AMD, DME, CRVO, and BRVO is enrolling as we speak. Next question.

Operator

Our next question comes from Ted Tenthoff from Piper Jaffray

Q - Ted Tenthoff {BIO 1880164 <GO>}

Great, thank you very much and my congrats too. Just when you come and look to the upcoming PDUFA dates in particular with respect to ZALTRAP, what are your preparations

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with Sanofi for potential launch there and what else should we be expecting from that program over the next 12 to 18 months?

A - Leonard Schleifer {BIO 1463677 <GO>}

Right. So I think that Sanofi is a highly experienced player in the oncology marketplace. They are taking the rowing oar on that. Obviously we work with them and we meet committees and all that, but we are going to rely heavily on their really outstanding experience in this area. In terms of what's to come over the next month, I think that George or I mentioned, that this is the beginning, we hope, of our entry into oncology. Clearly, we would like to make the effects of anti-VEGF therapy even better for patients. While there's clearly a survival effect in our studies, we would like to exceed a bigger effect and we think perhaps by combining it in a clever way with several of one or more of our anti-angiogenesis agents that are already in the clinic or trying to identify patients who might do better or not have side effects or what have you, we certainly are trying to amplify those effects. Next question.

Operator

Our next question comes from Phil Nadeau with Cowen and Co..

Q - Phil Nadeau {BIO 4838409 <GO>}

Thank you for taking my questions and let me add my congratulations on the quarter. A couple of follow-up questions

A - Leonard Schleifer {BIO 1463677 <GO>}

I missed that sorry you broke up here

Q - Phil Nadeau {BIO 4838409 <GO>}

Sorry. I just said let me add my congratulations on the quarter. Just some follow-up questions on the Q-code. Could you tell us from a physician or patient perspective how much easier it makes logistics prescribing EYLEA. Is there any less paperwork or is it just that the claims get paid back faster, and related to that if claims are getting paid back faster can you give us a sense of how much longer you're going to keep your expended payment terms?

A - Robert Terifay {BIO 4342122 <GO>}

Yes. So many of the carriers required under a period where we had a miscellaneous J-code additional paper work such a copies of the approval letter, documentation of the claim, the use for wet AMD, and that did require extra paperwork for the offices and often times there has been a change over in the computer systems to process claims and there has been a slowdown especially on these manual-type claims. So with the Q-code, many of the carriers have said they don't require that documentation up front anymore because there is now a specific code for EYLEA, so it is easier for many offices to file. And as we said, we have seen in some of the carriers around the country that we're slow on claims processing because of these manual procedures that we only got a Q-code on July 1st

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and we're seeing claims come will do already in some of those practices so it's very encouraging

A - Leonard Schleifer {BIO 1463677 <GO>}

I think we have time for one more question, operator.

Operator

Our next question comes from Jeff Meachum with JPMorgan.

Q - Jeff Meachum

Good morning, guys. Thanks for taking the question. Just a few on the PDGF. So you guys are in phase one next year. But I'm just curious if you actually selected a single antibody candidate so far and maybe anything you can tell us about what you've seen and model in combination with EYLEA and then the third part to this is I guess should we infer from the PDGF that your bias is to develop one organically and to not partner? Thanks

A - Leonard Schleifer {BIO 1463677 <GO>}

All great questions but I think we have probably said more than we are comfortable saying, frankly, I don't want to get into much more detail since it's a pretty competitive space, Jeff. Okay?

A - Michael Aberman {BIO 6989908 <GO>}

All right. So that wraps up the call for today. I want to thank you everyone for participating and everyone for calling in and we look forward to working with you in the coming quarters.

Operator

Ladies and gentlemen, this concludes today's presentation. You may now disconnect and have a wonderful day.

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