Q4 2011 Earnings Call

Company Participants

- Bob Terifay, SVP Commercial
- Leonard Schleifer, Founder, President, CEO
- Michael Aberman, VP
- Murray Goldberg, CFO

Other Participants

- Biren Amin, Analyst
- Chris Raymond, Analyst
- Geoff Meacham, Analyst
- Jason Kantor, Analyst
- Jim Birchenough, Analyst
- Josh Schimmer, Analyst
- Phil Nadeau, Analyst
- Steve Byrne, Analyst
- Unidentified Participant
- Yaron Werber, Analyst

Presentation

Operator

Good morning, ladies and gentlemen, welcome to the Regeneron Pharmaceuticals conference call to discuss the Fourth Quarter and full year 2011 financial results. My name is LaToya and I'll 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 the call. As a reminder, this call is being recorded for replay purposes.

I would now like turn the call over to Dr. Aberman, Vice President of Strategy and Investor Relations for Regeneron. Please proceed Dr. Aberman.

Michael Aberman {BIO 6989908 <GO>}

Thank you, very much. Good morning, and welcome to Regeneron Pharmaceuticals Fourth Quarter and full year 2011 conference call. An archive of this webcast will be available on our website under events and presentations for 30 days. Joining me on the call today is Dr. Leonard Schleifer, Founder, President and Chief Executive Officer, Murray Goldberg, Chief Financial Officer, and Robert Terifay, Senior Vice President of Commercial. After our prepared remarks, we will open the call for questions and answers.

I would like to also remind you that remarks made on this call that are not historical 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 business, sales forecast, 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 filings with the United States Security 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.

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 is available in our financial results press release which can be accessed on our website. Once our call concludes, the IR team will be available to answer further questions. With that, let me turn it over to our President and Chief Executive Officer, Dr. Len Schleifer.

Leonard Schleifer {BIO 1463677 <GO>}

Thank you, Michael, and good morning to everyone. I apologize in advance, I have a cold and a cough and there's been nothing coming from the labs to deal with it. I want to state that this is our very First Quarterly conference call, some of you may say it's about time, but we think now it's time we start as we transform ourselves into a commercial Company to start having these calls.

2011 was truly a transformational year for us. It was the year when we advanced our vision of becoming not only a fully integrated biopharmaceutical Company, or FIBPCO, but also hopefully a long-term biopharmaceutical growth Company. We submitted three BLAs in the US and celebrated the approval and launch of a potentially major product EYLEA.

We also reported positive Phase 2 results with two antibodies in our collaboration with Sanofi which are now in Phase 3 testing. In a survey conducted by the General Science, we were voted the second best biopharmaceutical Company to work for.

As we look forward to 2012, we see another exciting year ahead of us with the continued launch of EYLEA for wet AMD in the US and the potential for FDA approval for our products or product candidates in three new indications, EYLEA for central retinal vein occlusion, ZALTRAP for previously treated metastatic colorectal cancer and ARCALYST for the prevention of gout flares. Beyond the US, we see potential approvals and launches across the globe for both EYLEA and ZALTRAP with our partners Bayer HealthCare and Sanofi.

Turning to the launch of EYLEA for wet AMD in the US, we are pleased to report that the launch continues to go extraordinarily well and exceeds our expectations on many fronts. Only a relatively short time ago, in early January, we reported that our Fourth Quarter 2011 EYLEA sales where $24.8 million which was many fold higher than most analysts were predicting for the six weeks of sales at that time. We also provided a preliminary forecast for 2012 EYLEA US sales of $140 million to $160 million. As we said back then, this forecast was based on only six weeks of sales data.

With another six weeks of EYLEA sales results, we have some added confidence in the EYLEA sales trends. In the first six weeks of 2012 we have seen an increase in weekly demand from a large number of doctors and practices, good repeat ordering trends, favorable reimbursement trends and positive feedback from physicians.

In fact, we have now shipped over 30,000 vials to physicians offices since our launch in November. As a result, we are increasing our 2012 EYLEA net sales forecast from $140 million to $160 million up to $250 million to $300 million. To be clear, while we have an additional six weeks of information, the launch is still early and therefore there is significant uncertainty inherent in this forecast.

The benefit of less than monthly dosing with efficacy that is clinically equivalent to monthly ranibizumab appears to have resonated strongly with the AMD community, as has our pricing. We believe that EYLEA with it's less frequent dosing offers an attractive new treatment option that provides an important alternative to wet AMD patients and physicians.

With over 30,000 vials shipped to physicians, we are also gathering our post-market safety data to follow up our first post marketing safety report with the FDA. In doing that, we can report that there have been no new adverse events not seen in our clinical trials, described in our label or that were inconsistent with the known risks of intravitreal injection.

As many of you know, intravitreal injections with anti-VEGF therapy are associated with known complications particularly ocular complications such as endophthalmitis and retinal detachments. Posted injection intraocular inflammation, such as sterile endophthalmitis, is a known risk following intravitreal injections of anti-VEGF agents and triamcinolone, incidence rates that report in the literature and can vary from 0.2% to 0.3%, and has also been reported to occur in clusters.

There have been approximately 14 cases of adverse events consistent with sterile endophthalmitis and a single isolated case of culture positive endophthalmitis reported to Regeneron with the use of EYLEA since launch. This translates to a rate of 0.05% per injection, similar to that which was seen in our clinical trials and within the range that has been reported with other anti-VEGF agents.

11 out of the 14 cases of sterile endophthalmitis were reported by a single group practice of six retinal specialists, and 9 of these 11 cases were accounted for by a single physician within the practice. The cases could not be traced to a single lot of drug nor a single

delivery of commercial vials. Vials from the same lot have been used widely throughout the country including the other physicians in this practice.

Excluding this one practice, the rate of intraocular inflammation reported to Regeneron following EYLEA was approximately 0.01% or 1 in 10,000. We're working closely with the practice involved to better understand this cluster, and are in the process of disassembling the information we have learned to retinal physicians. We have informed the FDA, as per than normal course. To be clear, we do not believe that the data available indicate that EYLEA is responsible for this cluster.

In terms of reimbursement, the comprehensive program that we have rolled out including EYLEA for you and extended commercial terms have been very well received. We have now received reports of reimbursement from all of the regional Medicare administrative contractors, giving us confidence that payers do understand the importance of EYLEA as an option for patients with wet AMD.

We have also seen positive responses and reimbursement from many of the commercial payers. This is not to say that we don't have more work to do and do not face continued reimbursement hurdles until we receive a permit J-code, which is expected in January 2013.

While EYLEA and wet AMD is the focus in the near term, we view EYLEA as a pipeline within a product, and are working diligently towards advancing EYLEA in other indications, namely central retinal vein occlusion, where have filed a supplementary BLA and have been granted a PDUFA date of September 23, and diabetic macular edema, where we have two Phase 3 studies that are ongoing, one of which the US study is fully enrolled. We plan on initiating shortly a Phase 3 study in branched retinal vein occlusion.

Our ex-US collaborator Bayer HealthCare has submitted regulatory applications for EYLEA and in wet AMD in Europe, Japan and other countries, and we expect approval in these territories beginning the second half of this year. Bayer has also started a Phase 3 trial in wet AMD in China in the Fourth Quarter of 2011. We believe that this is an important market as evidenced by the fact that in 2010 there were approximately 540,000 newly diagnosed wet AMD patients over the age of 50 in China.

EYLEA is both a driver-- EYLEA is a driver both near term and long term value to the Company and shareholders, but Regeneron is more than just about EYLEA. We firmly believe that we have the key elements that are fundamental to achieving sustained long-term growth namely near and long-term revenue drivers, a pathway to profitability that is driven by the profit margins of our products and product candidates, an the attractive terms of our collaboration agreements, a wide, strong and rapidly advancing pipeline, and our solid infrastructure of people and manufacturing capabilities.

Our commitment to transform science into medicine is reflected in our robust and rapidly advancing pipeline. In 2011, we filed a supplemental BLA for ARCALYST for prevention of gout flares in patients initiating uric acid-lowering therapies and have been granted a PDUFA date of July 30 of this year. We also initiated UPSURGE, a long-term safety study of

ARCALYST. We along with our partner Sanofi have submitted a BLA for ZALTRAP for previously treated metastatic colorectal cancer for which we expect the regulatory decision in 2012. Sanofi has also filed a marketing application for ZALTRAP in the EU.

We also reported positive Phase 2 data from late stage-- two late stage antibodies in our pipeline, PCFK9 in hypercholesterolemia and Sarilumab, our IL-6 receptor in rheumatoid arthritis and have advanced two new antibodies into the clinic. Both the PCSK9 and the Sarilumab programs are continuing to advance to Phase 3 this year. Both programs address significant market opportunities. We look forward to presenting results from two of the Phase 2 PCSK9 trials at the upcoming American College of Cardiology meeting where one of the trials will be presented in the late breaker session.

Our pipeline now has a total of 10 antibodies in the clinic, 8 of which are being developed in collaboration with Sanofi. At Regeneron, we've always believed that good science wins out and the approval of EYLEA was proof of the validity of this belief. We are well positioned to continue to make important advances in therapeutic areas where there is unmet need and significant commercial opportunity. With that, I would like to now turn the call over to Murray Goldberg, our Chief Financial Officer, who will review our Fourth Quarter and full year financial results.

Murray Goldberg {BIO 1463711 <GO>}

Thank you, Len, and good morning to everyone. This morning we reported total revenues in 2011 of about $446 million for the full year and $123 million for the Fourth Quarter. In the Fourth Quarter, this includes net product sales of $24.8 million for EYLEA and $5 million for ARCALYST. Our gross to net adjustment for EYLEA was 7.3%. Cost of goods sold in the Fourth Quarter was $3 million, or about 10% of net product sales.

This includes an accrual for royalties payable to Genentech under the license and partial settlement agreement that we signed in December relating to ophthalmic sales of EYLEA in the United States. From a cash perspective, we're not obligated to make any payments to Genentech until cumulative US sales reach $400 million. Then we'll make a one-time payment of $60 million.

Thereafter, we'll pay royalties until May 7 of 2016 of 4.75% on cumulative sales between $400 million and $3 billion and 5.5% on cumulative sales over $3 billion. In terms of accounting for these payments, we are accruing royalty expense as we recognize sales of EYLEA using a blended mid single-digit royalty rate that reflects both the $60 million payment and royalty obligations based on our estimate of cumulative sales through May 7, 2016.

Non-GAAP research and development expenses rose 6.4% in 2011 to about $497 million, principally in connection with our Sanofi antibody collaboration. Non-GAAP SG&A expenses doubled in 2011 to $94 million, primarily related to the commercialization of EYLEA. We expect further increases in SG&A expenses in 2012 as we prepare for the launch of ARCALYST for the treatment of gout flares. Non-GAAP R&D and SG&A expenses exclude non-cash share-based compensation expense.

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