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.

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 intravitrial 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.

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 opthalmology 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

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.

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 I 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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