

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.

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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.

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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 were \$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 its less frequent dosing offers an attractive new treatment option that provides an important alternative to wet AMD patients and physicians.

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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. Post 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

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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

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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, PCSK9 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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We reported and non-GAAP net loss of \$34 million, or \$0.37 per share for the Fourth Quarter, and a non-GAAP net loss of \$161.7 million, or \$1.79 per share for the full year 2011. Non-GAAP net loss excludes non-cash share-based compensation expense and non-cash interest expense related to our convertible senior notes.

For the Fourth Quarter we reported a GAAP net loss of \$53.4 million, or \$0.58 per share. For the full year 2011, we reported a GAAP net loss of \$221.8 million, or \$2.45 per share, compared to a net loss of \$104.5 million, or \$1.26 per share for the full year 2010. All of these per share values are for both basic and diluted per share calculations.

In October 2011, we completed a private offering of \$400 million aggregate principal amount of 1.875% convertible senior notes. Following this, we ended 2011 with approximately \$811 million in cash and securities. We believe that financially we're in a comfortable position to support the required investment not only for the continued commercial launch of EYLEA but also for the launch of ARCALYST in gout and ZALTRAP in colorectal cancer, as well as for advancing our pipeline and driving us toward profitability.

In terms of financial guidance as you heard from Len, we're updating our EYLEA net sales forecast from the previous \$140 million to \$160 million to a new range of \$250 million to \$300 million. We continue to expect COGS for EYLEA, including royalty expense, to be under 10% of net sales. Thank you, and with that, I will turn the call back to Michael.

Michael Aberman {BIO 6989908 <GO>}

Thank you, Murray, and thank you, Len. That concludes our prepared remarks, we'd now like to open the call for Q&A. As we'd like to give as many people a chance to ask a question as possible, we request you limit yourself to one question and our team will be available in our office after the call for follow-up questions. Thank you, and Operator, can you please give instructions and open the call for questions?

Questions And Answers

Operator

(Operator Instructions) Jim Birchenough of BMO Capital.

Q - Jim Birchenough {BIO 5068439 <GO>}

Hi, guys, congratulations on the strong launch. I just wanted to follow up on the sterile endophthalmitis clustering at that one center. Is there any working hypothesis and what might be underlying that and I'm interested in particular if whether these cases were in treatment naive patients or in switch patients and maybe just a bit more detail on that would be helpful? Thanks.

A - Leonard Schleifer {BIO 1463677 <GO>}

Thanks, Jim. What we know so-- there's no firm hypothesis at this point. We're looking at everything, we do know that these patients we believe they were switched from both of

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that Lucentis, the doctors there are experienced so we're not sure what's different. We do know that they're using a different needle than the one that we supply, we don't know if that's the issue. Frankly, these clusters occur and sometimes you just never figure it out, but we're continuing to do this. They were also in naive patients and well. I'll tell you this and remind you that when you give 30,000 injections you expect to get some rate of sterile intraocular information as just a fact of intravitreal injections and these things tend to occur in clusters and sometimes people figure it out. You'll see in (inaudible) FDA that one person figured it out it was-- one group figured out it was a needle, another group could never figure out what it was. So we're going to continue to try and figure this one out as well.

Q - Jim Birchenough {BIO 5068439 <GO>}

Okay, thanks, Len.

Operator

Jason Kantor of RBC Capital Markets.

Q - Jason Kantor {BIO 1957973 <GO>}

Thank you, and congratulations as well. Just a couple questions on the launch and how you're tracking it. I'm wondering as you're doing your guidance, what are your assumptions for kind of the drop off in the rate of injections going from the once-a-month for three months then dropping off, are you assuming that there's a flattening or even a down quarter at any point this year? And I guess when you're looking at what patients are coming on the drug, how many of these are switching versus newly diagnosed or naive patients? And is the market actually going with the introduction of EYLEA because more people are coming back on the therapy?

A - Leonard Schleifer {BIO 1463677 <GO>}

So, Jason, thanks for your questions, you've asked all the questions that I've been asking, unfortunately, I haven't been getting answers because we don't really have the answers. We are seeing a significant amount of switching. So we don't know for those patients how many doses they'll actually get. We are seeing new patients. We don't know what the practice pattern will be out there. We have modeled this in a variety of ways and as I said, these forecasts have inherent uncertainty in them. I wish I could give you more specifics, we just don't have them.

Q - Jason Kantor {BIO 1957973 <GO>}

You don't have any sense of what percentage of your patients are coming from -- are switching from other drugs or--?

A - Leonard Schleifer {BIO 1463677 <GO>}

My guess is that the majority are coming from switches. We've heard lots of comments that people are switching even in more difficult patients. But we don't have any formal data yet.

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Q - Jason Kantor {BIO 1957973 <GO>}

Thank you.

A - Leonard Schleifer {BIO 1463677 <GO>}

Okay.

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Operator

Josh Schimmer of Leerink.

Q - Josh Schimmer {BIO 6783077 <GO>}

Hi, thanks for taking the question, congrats as well on a strong launch. Maybe you can give us a little bit of color in terms of the reimbursement process, what hiccups, if any, are out there? If you're expecting that to improve over the course of the year? And what feedback you have from the specialists in terms of their comfort level at this point with reimbursement and whether that's going to improve over the year as well?

A - Leonard Schleifer {BIO 1463677 <GO>}

Thanks for your question, Josh, I'll turn it to Bob Terifay, our Head of Commercial to answer that, please.

A - Bob Terifay {BIO 4342122 <GO>}

Yes, so as Len pointed out in the conference call, the Medicare carriers are all now reimbursing for EYLEA, and as you know the vast majority of these patients are covered by Medicare. We also do you have reports of commercial coverage. The real concern that offices have before they widely adopt the product is to ensure that not only is the 80% covered by Medicare reimbursed, but also that the patient co-pay is covered. We are seeing the co-pays work through although the insurers that cover co-pays don't move as quickly to change their system. So that is resulting in offices going slowly upfront to make sure that they're going to get reimbursed. And that'll be the situation over the next several months until all the coverage settles out.

But as I say, the Medicare carriers are covering, we are seeing more and more commercial payers coming on board and thus far the offices are beginning to see the payments come in. So actually things are where we would have expected at this point in a launch with a temporary J-code.

Q - Josh Schimmer {BIO 6783077 <GO>}

And does your guidance assume growing comfort with reimbursement or are you just still kind of waiting to see how that goes as well?

A - Leonard Schleifer {BIO 1463677 <GO>}

Our guidance tries to take into account all of those factors, Josh. But as you can imagine, there's so many unknowns, certainly there's some impediment to this launch because of a

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lack of a permanent J-code and some of these reimbursement issues, co-pays and what have you. Nevertheless, it launch is going pretty well. But a lot of uncertainties in terms of dose-- number of doses, how may people load-- are going to be loaded, will doctors hopefully file the label or will they do the treat and extend or some other paradigm, these are-- we've tried our best to model all of this, that's how we came up with the new guidance for you.

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Q - Josh Schimmer {BIO 6783077 <GO>}

Thanks so much.

A - Leonard Schleifer {BIO 1463677 <GO>}

Thank you.

Operator

Robyn Karnauskas of Deutsche Bank.

Q - Unidentified Participant

Hello there, it is Olivia in for Robyn today. Congrats on a great guidance, just a couple questions on the specifics on EYLEA,. But the run rate looks very strong, but how penetrated is the drug in the community versus bigger (stars) and just similar, how big a factor was stocking in doctors offices and what your expectation on that?

A - Leonard Schleifer {BIO 1463677 <GO>}

So maybe I'll cover the second and Bob will cover the first. In terms of stocking, our estimate is the doctors don't keep much supply at all, perhaps a week at most. Of the distributors, maybe one to two weeks at most I would say. Now in terms of the other part of your question in terms of-- Bob, you want to deal with that?

A - Bob Terifay {BIO 4342122 <GO>}

So in terms of penetration into practices, what we do know is that approximately 38% of practices that by Lucentis have bought EYLEA. So we have penetrated the offices pretty well and we do see a good distribution of our usage across practices.

Q - Unidentified Participant

Great. Thanks.

Operator

Chris Raymond of Robert W. Baird.

Q - Chris Raymond {BIO 4690861 <GO>}

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Thanks for taking the question. I just wanted to make sure I understand the math a little bit here. So, and I jumped on a little bit late, so if you guys cover this already, but if I count 30,000 vials that you shipped so far and you back out the first-- the last six weeks of 2011, are we talking 20,000 vials through mid-February, is that kind of way the math goes?

A - Murray Goldberg {BIO 1463711 <GO>}

Yes, 30,000 minus 10,000 is 20,000, correct. We'll go with that.

Q - Chris Raymond {BIO 4690861 <GO>}

And so-- thank you. And so are we thinking that, so than your numbers if you think about gross to net adjustments et cetera that you're talking roughly \$34 million for the first six weeks of the year?

A - Murray Goldberg {BIO 1463711 <GO>}

I'll let you do the math because I don't want to be nailed down to specifics et cetera, et cetera, but I think you're basically on the right track.

Q - Chris Raymond {BIO 4690861 <GO>}

And was there any dynamic between weekly numbers beginning of the year to say mid-February?

A - Leonard Schleifer {BIO 1463677 <GO>}

Yes, that I can't tell you but I can tell you from the first six weeks to the last six weeks, so before the new year to after the new year, there was definitely a pickup after the new year. And not surprising because a lot of docs, first of all, it was a brand-new launch second of all, coverage tends to change for patients around the end of the year and so a lot of docs actually waited until after the new year, so once they started treatment they knew their coverage wouldn't be changing out from under the patient. So we definitely saw an uptick in increase in the rate from pre-new year to post new year.

Q - Chris Raymond {BIO 4690861 <GO>}

Thanks.

Operator

Steve Byrne of Bank of America.

Q - Steve Byrne {BIO 7019262 <GO>}

Hi, Len, you mentioned the incidence of wet AMD in China, when you consider just total prevalence in that country and taking into consideration government and/or private payer coverage in those larger cities, how would you estimate the market opportunity in China say versus Europe?

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A - Leonard Schleifer {BIO 1463677 <GO>}

Yes, that's a great question. I don't really know how to do that one and I haven't been focused on it because this is something that Bayer takes the rowing oar on for us in our partnership. While we've split the profits 50/50 outside of the United States, and we are obviously very interested, they do the mechanics out there and so-- and they're much more in touch with these markets. We can try and ask them and get back to, Steve, I don't know the answer.

Q - Steve Byrne {BIO 7019262 <GO>}

And just to follow on to that, do you view that 300 patient study in China as being sufficient for approval?

A - Leonard Schleifer {BIO 1463677 <GO>}

I think also we should defer that question to Bayer, I'll find out. I think that the goal would be that when you combine it with our other studies and you have a Phase 3 study there that we would hope we could get approval.

Q - Steve Byrne {BIO 7019262 <GO>}

Thank you.

Operator

Biren Amin of Jefferies.

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Q - Biren Amin {BIO 7512048 <GO>}

Yes, thanks for taking my questions and congratulations on the quarter. I was curious, what dynamics are driving the switching from Lucentis to EYLEA? And also has any Medicare plans denied reimbursement to date that you know of? Thanks.

A - Leonard Schleifer {BIO 1463677 <GO>}

Right, so as far as the switching goes, I imagine, and we've been to several of the medical meetings where we've heard this, that the patients who do not get what the doctors consider an adequate response to either Lucentis or Avastin, because there's been switches to both, are looking to try something that might give them the patients an opportunity to do better. That's fairly a typical dynamic when a new product comes to the marketplace. Many doctors will look at they are difficult to treat or patients they don't think are doing (aptly) well. And I want to say this, we see this both in Lucentis and Avastin patients. So I would have to say that that's the-- that dynamic is definitely at play here. But Bob, do you want to address the other question about reimbursement?

A - Bob Terifay {BIO 4342122 <GO>}

In terms of any rejections, in the presence of a miscellaneous J-code there are two potential codes that can be processed on the paperwork for a given insurer. And sometimes if somebody marks down one of them, that particular insurer will not process

the paperwork. So what we have seen is that claims have been sent back to offices and then we work through the appeals process. So it seems to be primarily paperwork oriented, we have had no outright rejections of EYLEA at the current time.

Q - Biren Amin {BIO 7512048 <GO>}

Fantastic. Thank you.

Operator

Monie Mohinger[ph] of ThinkEquity.

Q - Unidentified Participant

Hi, thanks for taking this call and a great first call. Quick question, I saw that you mentioned that you're expanding into BRVO, could you elaborate a little bit more on the opportunity in the BRVO market?

A - Leonard Schleifer {BIO 1463677 <GO>}

Bob, do you want to just in terms of the number of patients and things like that approximate, do we have that?

Q - Unidentified Participant

All Lucentis is doing there and what kind of market it opens up for you beyond wet AMD and the CRVO?

A - Bob Terifay {BIO 4342122 <GO>}

So I'll give you a broad -- the BRVO in terms of market size falls in between the size of the CRVO market in the AMD market. So it will add a fairly substantial additional market opportunity for EYLEA. As you mentioned, Lucentis is now approved in branch retinal vein occlusion and patients, or people have-- physicians are responding very well to the use of anti-VEGF in that setting.

Q - Unidentified Participant

Thank you, I'll step back in the queue.

Operator

Yaron Werber with Citigroup.

Q - Yaron Werber {BIO 19486720 <GO>}

Great, thanks so much and congrats there, nice launch. (inaudible) I'm going to sneak in very two quick questions, just AMD and DME, I'm not sure if you can answer at all, are you seeing any usage yet kind of off label in that setting? And then I had a question about expenses, if you don't mind.

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A - Leonard Schleifer {BIO 1463677 <GO>}

As far as we know the predominant use of the product is in AMD and of course we don't discuss that, we don't promote it, so we really wouldn't even be in a position to get feedback if they were using it. But from what we hear, spontaneously at the conferences and what have you, the discussion is centered virtually completely around AMD as it should. Now I didn't hear your second question, Yaron.

Q - Yaron Werber {BIO 19486720 <GO>}

So I have a question on depending on what we model, I mean if you look at the model, the two biggest questions number one what's (inaudible), but you've given us great color there. So we can kind of start thinking about what are you going to record from the collaboration revenue with Sanofi and then kind of what your expenses are going to be, but I guess where I'm going with this is there any scenario by which you can be profitable this year?

A - Leonard Schleifer {BIO 1463677 <GO>}

Murray?

A - Murray Goldberg {BIO 1463711 <GO>}

Let me first comment in terms of your question about R&D, which is obviously the largest expense item on our income statement. For the most part at this point it is-- those expenses are related to with the antibody collaboration and those are reimbursed by Sanofi, so they're two big numbers, the R&D expense and the reimbursement from Sanofi. But for the most part they offset to the extent they're related to the antibody collaboration.

Is there a scenario in which we could be profitable this year? There is depending obviously on how big EYLEA sales are. As we pointed out earlier, the gross margin on EYLEA sales is quite high, 90% or so. And so depending on how large EYLEA sales where, we could be there. But in terms of the forecast sales that we provided today of \$250 million to \$300 million, we do not believe that that would get us there with the usual caveats of depending on what happens to other R&D expenses that are not reimbursed, et cetera.

Q - Yaron Werber {BIO 19486720 <GO>}

Great, thank you.

Operator

Geoff Meacham of JPMorgan.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hi, guys, thanks for taking the question. Just wanted on the intraocular inflammation, I guess it seems like it's fairly common i.e. for the class, but it'd be helpful to get a history

here, was this something that you guys picked up from this field on your own, or is this something that the FDA saw in the (inaudible) database that kind of prompted you guys? And I have a quick follow up.

A - Leonard Schleifer {BIO 1463677 <GO>}

No, we picked this through reporting-- that report that come directly to the Company and we've been in contact with our medical affairs people with the specific practice as we saw this cluster beginning to emerge. You had a second question?

Q - Geoff Meacham {BIO 21252662 <GO>}

Yes, second question just is anything else that you've seen beyond the intraocular inflammation that is different from the Phase 3s just on the adverse event side?

A - Leonard Schleifer {BIO 1463677 <GO>}

No we've -- there's no signals at all, Geoff. And even this intraocular inflammation is something, if you look in the letter we sent off to the agency, you can see we give the history there, that we've seen intraocular inflammation in our trials and frankly, it's been well reported in the literature and you talk to experienced retinal physicians, they all tell you they see it on occasion.

Q - Geoff Meacham {BIO 21252662 <GO>}

Okay, thanks.

A - Leonard Schleifer {BIO 1463677 <GO>}

You're welcome.

Operator

Phil Nadeau of Cowen and Company.

Q - Phil Nadeau {BIO 4838409 <GO>}

Good morning, let me add my congratulations on the launch. Question on 727 and the PCSKA9 class, there's a potential competitor of yours out there who's saying that the FDA sent letters to all the PCSK9 developers, and this competitor characterized the letters as basically requiring event studies for approval. I was curious to whether you or Sanofi has received such a letter and whether you characterize it the same way? Do you think that event studies will be necessary?

A - Leonard Schleifer {BIO 1463677 <GO>}

No, I think you may be mixing up two things, but the only letter that's been we know circulated is some general comments that a pre-clinical reviewer had on largely based on pre-clinical theoretical data of what happens if you lower cholesterol too much and suggesting some pre-clinical experiments that we should use to address them. And if we didn't, that that would be a labeling type issue. As far as outcome studies we have not

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received any communication and I don't believe any other competitor has said publicly that we're aware of that they received a communication that an outcome study will be required prior to approval.

As for our working assumption now based on our conversations, but obviously these things can change, our working assumption is that we would have a large Phase 3 safety and efficacy database and at the time of our submission and obviously approval we would be well underway for an outcome study but that outcome study would not be a required prior to approval. Of course, if the FDA sees something in the safety database that raises questions, then they could switch appropriately so to require an outcome study. But as of now, we don't believe that's going to be necessary prior to initial approval.

Q - Phil Nadeau {BIO 4838409 <GO>}

Okay. Great. Thanks for answering the question.

A - Leonard Schleifer {BIO 1463677 <GO>}

Thank you.

Operator

Jim Birchenough of BMO Capital.

A - Michael Aberman {BIO 6989908 <GO>}

And Operator this is going to be the last question.

Q - Jim Birchenough {BIO 5068439 <GO>}

Hello, guys, thanks for letting me get back in with a follow up. Just so maybe for Bob, just trying to get an understanding of potentially detail here and that would be profitable formularies where you're trying to get EYLEA on formulary. It doesn't happen immediately, we're hearing about some centers that are finally getting EYLEA on formulary, can you give us a sense of what penetration you have there, Bob?

A - Bob Terifay {BIO 4342122 <GO>}

As you pointed out, Jim, we are starting to see the major I centers come onboard with formulary approvals, but several institutions take several months. So I can't quantify the percent of hospital formularies, but I can tell you that some of the major centers have come on within the last few weeks.

Q - Jim Birchenough {BIO 5068439 <GO>}

All right, thanks, guys.

A - Michael Aberman {BIO 6989908 <GO>}

Okay, Operator, I think we're going to conclude the call with that.

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Operator

Ladies and gentlemen, thank you for participating in today's conference. This concludes the program, you may now disconnect. Good day.

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