

Q1 2012 Earnings Call

Company Participants

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

Other Participants

- Biren Amin, Analyst
- Chris Raymond, Analyst
- Geoff Meacham, Analyst
- Jason Kantor, Analyst
- Jim Birchenough, Analyst
- Kumar Venkatesaran, Analyst
- Manny Mahinscher, Analyst
- Phil Nadeau, Analyst
- Robyn Karnauskas, Analyst
- Steve Byrne, Analyst
- Terence Flynn, Analyst

Presentation

Operator

Good morning, ladies and gentlemen, and welcome to the Regeneron Pharmaceuticals conference call to discuss the First Quarter 2012 financial results. My name is Kevin 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 this 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 and Investor Relations for Regeneron. Please proceed, Dr. Aberman.

Michael Aberman {BIO 6989908 <GO>}

Thank you, Kevin. Good morning, and welcome to Regeneron Pharmaceuticals' First Quarter 2012 conference call. An archive of this webcast will be available on our website under the event and presentation page for 30 days.

Samsung v. Regeneron
IPR2023-00442
U.S. Pat. 10,130,681
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Joining me on the call today is Dr. Leonard Schleifer, Founder, President and Chief Executive Officer; George Yancopoulos, Chief Scientific Officer and President of Regeneron Research Labs; Murray Goldberg, Chief Financial Officer; and Robert Terifay, Senior Vice President Commercial. After our preferred 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 business, sales forecast, financial 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 Securities and Exchange Commission, or SEC, including its Form 10-K for the year ended December 31, 2011, and Form 10-Q for the quarter ended March 31, 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 event or otherwise unless required by law. GAAP and non-GAAP measures will be discussed on today's call. Information regarding our use of a non-GAAP financial measures and a reconciliation of these measures to GAAP are available in our financial results press releases which can be obtained on our website. Once our call concludes, 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. Len Schleifer.

Len Schleifer

Thanks, Michael, and good morning to everyone. Before I get to the meat of today's call, on the occasion of today's milestone for Regeneron I would like to say a few thank-yous as surely many thanks are owed to many, many people. I offer these thanks on behalf of both me and my good friend, George Yancopoulos. As most of you know, George is the lead inventor of EYLEA and is, in fact, responsible for our entire pipeline and technologies. George and I embarked on this professional partnership and exciting journey together many years ago with the firm belief that good science would lead to good drugs. I believe we were right, although predicting the exact timing of things, as you well know, can be rather challenging.

In any case, we owe great debts of gratitude to all of our colleagues over the years who have dedicated themselves to bringing drugs to patients, as well as to the thousands and thousands of patients who have volunteered for our clinical studies. We are also greatly indebted to the physicians and the medical community for helping us with all of our clinical trials and for the partnership we have had with the FDA as we navigated the development process. Finally, thanks to our partners and all of our shareholders who have believed in us and helped finance our efforts. Now, back to business.

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Today we're happy to report a very successful quarter and a true milestone for Regeneron as it was the First Quarter in our history that we achieved profitability both on the GAAP and non-GAAP basis as a result of product sales. This achievement was driven by the continued strong launch of EYLEA in the United States. EYLEA's unique product profile as the only FDA approved treatment for wet AMD labeled for less than monthly dosing that showed clinically equivalent efficacy to monthly ranibizumab continues to resonate with patients and their caregivers, physicians and payers.

As a result of this strong launch and First Quarter sales of \$124 million, we are increasing our full-year US EYLEA net sales forecast to be between \$500 million and \$550 million. Meeting of this forecast would place EYLEA among the most successful biotech launches. Given this new forecast as well as our strong profit margin and the terms of our agreements with collaborators who fund a large portion of our R&D expenses, we also now believe we will achieve non-GAAP profitability for the full year 2012. Before we get into some of the details behind the launch and our updated forecast, let me highlight some other important accomplishments during this quarter.

Turning first to our late-stage assets, the FDA recently granted priority review status to the ZALTRAP BLA for the treatment of previously treated metastatic colorectal cancer. We now have expect three FDA decisions for our drug candidates in the second half of the year, ARCALYST for the prevention of gout flares in patients initiating uric acid lowering therapy which had a PDUFA date of July 30. ZALTRAP for the treatment of previously treated metastatic colorectal cancer which has a PDUFA due date of August 4, and EYLEA for the treatment of central retinal vein occlusion, or CRVO, which has a PDUFA date of September 23. Our regulatory department has never been busier with the FDA on these applications as well as preparing for the upcoming ARCALYST advisory committee meeting scheduled for May 8.

Turning to our antibody pipeline, we have seen significant interest in the scientific and clinical communities in our potentially first-in-class lipid lowering PCSK9 antibody, REGN727, which is part of our collaboration with a Sanofi. During the quarter we saw Phase 1 data published in the New England Journal of Medicine and Phase 2 data presented at the annual meeting of the American College of Cardiology including during a late-breaking clinical trial session.

The data, which showed up to a 72% decrease in LDL cholesterol or bad cholesterol, when adding REGN727 on top of existing statin therapy was encouraging to us and to many of the expert cardiologists who are seeing the data for the first time. This high level of interest was also evident in the broad media coverage of these publications and presentations. As we've discussed previously, Regeneron 727 demonstrated an acceptable profile in these studies, acceptable safety profile in these studies. There is still much work to be done in our anti-PCSK9 program as the data we presented were from Phase 2 trials. As such, we and Sanofi look forward to initiating our full Phase 3 program to further evaluate the efficacy and safety of 727 later in the Second Quarter following feedback from US and European regulatory agencies.

Another positive development from our pipeline this quarter was the FDA advisory committee's unanimous vote in favor of the ongoing development of anti-nerve growth

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factor, anti-NGF agents in pain associated with osteoarthritis. We believe there could be an important role for these agents in the treatment of this pain and we hope to be able to provide an update on our development plans for our NGF antibody, REGN475, in the next few months after discussions with the FDA. As a reminder, Regeneron now has sole rights to REGN475 with a royalty obligation to Sanofi.

With that, let me turn back to the EYLEA launch which we can report continues to exceed expectations. Net product sales to our distributors for the First Quarter 2012 were \$124 million which includes a modest increase in our distributors inventory of about \$10 million. This implies approximately \$114 million in sales to healthcare providers. Market research suggests the strong launch has been driven by several factors including the high market awareness of EYLEA, physician and patient's belief in the value of achieving clinically equivalent efficacy to monthly ranibizumab with less than monthly dosing and their experience with EYLEA since the launch.

Also, the favorable perception of Regeneron as a pharmaceutical company, the belief that we are a different kind of company, that we listen to and deal openly and candidly with the patient, physician and payer communities is an important factor. As we reported before, another important factor contributing to the strong EYLEA uptake is that we are penetrating both the community of patients who are initiating therapy for wet AMD for the first time as well as patients switching from existing therapies as I will describe in a moment. So, let me turn to some of the metrics that we can share about the launch.

Our market research has been relatively consistent with what we have seen from survey work done outside the Company such as the never-ending surveys reported by the investment community. Specifically, our survey data suggested approximately 40% of EYLEA patients are new to anti-VEGF therapy. This means that about 60% of EYLEA use has come from patients switching from other therapies. Importantly, prior Lucentis users account for the majority of switches at roughly 60% but prior Avastin users are an important contributor at roughly 40%. The most common reasons physicians report for why they switch patients to EYLEA are continued retinal edema despite treatment with Lucentis or Avastin, and non-optical[ph] response to existing therapy and the desire to have less frequent injections and/or office visits.

In terms of our field force, we've been very pleased by the effectiveness and the reception they have received from the retinal community. As expected at this stage in the launch, we have seen rapid growth in the number of retinal practices ordering EYLEA and our distributors have now shipped EYLEA to more than 70% of the practices known to us to have used Lucentis in the past. While the launch is going well, reimbursement concerns for many issue for many doctors particularly while we wait for permanent J code which we expect to be assigned in January 2013.

Meanwhile, extended terms are available to physicians' offices to allow ample time for them to receive reimbursement for EYLEA. We also expect reimbursement concerns to be alleviated by two recent developments. Since April 1, hospital outpatient facilities have been able to use a temporary C code for EYLEA which automates the reimbursement process for this group of users. In addition, EYLEA has been assigned a Q code that goes into effect this July. The Q code is a temporary but specific code for EYLEA that can be

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used more broadly than the C code and which results in automated reimbursement. We believe that this will help streamline the reimbursement process as we await the assignment of a permanent J code. As we've said before, we have seen reimbursement from all of the regional Medicare carriers, secondary and supplemental insurers, commercial payers and private payers. We've also seen broad adoption by hospital formulas.

As indicated earlier, we are increasing our full year 2012 EYLEA net sales forecast from \$250 million to \$300 million to \$500 million to \$550 million. So, let me spend a few moments on this updated forecast. There are three types of patients that will influence our continued sales and growth. The first is the new patients who are naive to therapy, the second is new patients to EYLEA who are switching from existing anti-VEGF therapy, and the third are patients who have already been started on EYLEA, the continuing patients.

For the first group, new naive patients, we expect continued growth at some practices who have only started trying EYLEA expanding to more patients as well as continued growth in the early adopters. Here, reimbursement issues will remain a tempering factor. For the second group, new switches, we expect continued growth but there is some uncertainty as to how big this patient population is. For both of these new patient groups, given our 70% level of penetration of physicians' offices, we can now -- we can also now expect a slowdown in the rate of new account growth.

Lastly are the patients who have already switched and started on EYLEA. Our market research suggests that the majority of these patients will be treated with three initial monthly doses followed by less frequent dosing regimens. On the one hand, continued patient use of EYLEA provides an ongoing source of revenue but the switch to less frequent dosing and potential discontinuations may moderate growth. The bottom line is that it is important to remember that EYLEA has been on the market for less than six months. We are really still in the early stages of this product launch with many uncertainties.

In the First Quarter a survey suggested EYLEA is capturing approximately 10% of the anti-VEGF market for wet AMD including off-label Avastin which accounts for approximately 60% of that market. We believe there is room for continued growth as many of the practices that have ordered EYLEA have ordered only limited quantities and could increase their use as they gain experience and are reassured that there will be no major reimbursement issues. That said, there are factors such as the switch by existing EYLEA users to less frequent dosing regimens as I discussed a moment ago, that could moderate growth.

Beyond the wet AMD launch in the United States, later this year we expect an FDA decision on our supplemental BLA to expand use of EYLEA to CRVO and by our healthcare plans to launch EYLEA into international markets. With that, I would now like to turn the call over to Murray Goldberg, our Chief Financial Officer, who will review our First Quarter financial results.

Murray Goldberg {BIO 1463711 <GO>}

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Thank you, Len, and good morning, everyone. As you might imagine, I'm particularly pleased to discuss our financial results for the First Quarter of 2012, the first time in Regeneron's history that we reported a profitable quarter on an operational basis. Total revenues in the First Quarter were \$232 million. This includes \$124 million of EYLEA net sales and \$4 million of ARCALYST sales. The gross-to-net adjustment for EYLEA sales was similar to last quarter at approximately 7.4%. Sanofi collaboration revenue was \$85 million for the First Quarter of 2012 which was similar to the First Quarter last year. This item includes Sanofi's reimbursement to us for antibody and ZALTRAP R&D expenses that we incurred, offset by approximately \$4 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 will include growing pre-commercial 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 an approval milestone. Buyer collaboration revenue is about \$12.5 million in the First Quarter and represents buyers cost sharing of some of the EYLEA development expenses that we incurred. As EYLEA launches globally, this item will also include our share of the profits and losses from commercialization outside the United States as well as a potential approval and sales milestones from buyer.

Cost of goods sold in the First Quarter was \$12.3 million or about 9.6% 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. Non-GAAP research and development expense was \$128 million for the First Quarter this year compared to \$122 million in the First Quarter last year. The increase in R&D spending was driven primarily by higher R&D headcount and activities, partly related to our antibody collaboration with Sanofi and partly related to our own internal R&D efforts.

To provide some perspective on the amount that we spend on internal R&D programs that is not reimbursed, start with the \$128 million of First Quarter R&D expense which excludes non-cash compensation expense. Sanofi reimbursed \$84 million of this expense and buyer reimbursed another \$10 million. So, our First Quarter net R&D expense was \$34 million this year compared to \$31 million last year. Thus, almost 75% of our R&D expense in the First Quarter was reimbursed by our collaborators, a similar percentage was reimbursed for all of 2011.

Our net R&D expense primarily represents spending on ARCALYST, on antibodies not in the Sanofi collaboration, some EYLEA clinical costs and investments in new discovery technology. We anticipate that this net R&D expense will trend upward through the remainder of 2012 and could increase even faster as antibodies outside the Sanofi collaboration, such as our NGF antibody, Regeneron 475, moves into advanced stage clinical trials. Let me also point out that not reflected in the \$128 million total R&D number is the considerable spending by Sanofi and buyer on our collaboration programs that does not flow through our income statement.

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In 2011, that averaged around \$50 million in quarter. Non-GAAP SG&A expenses were \$46 million for the First Quarter. These SG&A expenses include the fully burdened cost of the EYLEA field force. While we do not expect EYLEA's selling expenses to vary significantly quarter-to-quarter this year. In the event that ARCALYST is approved for the prevention of gout flares in patients initiating uric acid lowering therapy, we anticipate that SG&A expenses could increase by \$20 million to \$30 million in the second half year to support the launch. This would bring full-year non-GAAP SG&A to \$180 million to \$210 million with the higher end of that guidance reflecting the potential ARCALYST launch in gout. As a reminder, non-GAAP R&D and non-GAAP SG&A expenses exclude non-cash share-based compensation expense.

Turning with some delight to the bottom line, we reported non-GAAP net income of \$40 million or \$0.37 per diluted share for the First Quarter of 2012. Non-GAAP net income excludes non-cash share-based compensation expense and non-cash interest expense related to our convertible notes. On a GAAP basis, we also had a profitable quarter with net income of \$12 million or \$0.11 per diluted share. 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 profits, we will provide more guidance on the accounting treatment of these and NOL's 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 average shares outstanding in the First Quarter were approximately 112.5 million shares. Include about 14 million shares attributable to stock options and restricted stock that are accounted for using the treasury method, and about 5 million shares associated with our convertible notes that are accounted for using the if-converted method. With that, I will turn the call back to Michael.

Michael Aberman {BIO 6989908 <GO>}

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

Questions And Answers

Operator

(Operator Instructions) Our first question comes from Robyn Karnauskas with Deutsche Bank.

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Hi, guys. Congratulations on making my very busy morning. Great launch. The key question I have for you is you talk a lot about 70% penetration in new physician offices but

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it really implies that you are really being used in a fraction of patients. Can you give some color on where you think EYLEA is being used amongst the doctor community? Is it in more large practices or are the community practices starting to use of EYLEA more? And where do you think the growth will come from? Thanks.

A - Len Schleifer

Bob, you want to comment on that?

A - Bob Terifay {BIO 4342122 <GO>}

So, we are actually seeing a very good distribution of EYLEA use in all types of practices. The large volume practices, the academic practices as well as a number of practices who don't broadly use Lucentis who have used -- who have switched from Avastin to EYLEA. So, we are very encouraged about the use. As Len pointed out, what we're still waiting to see, and reimbursement is one of those hurdles, physicians are holding back a little bit on how much EYLEA they use, but we do have very good penetration in all segments.

A - Michael Aberman {BIO 6989908 <GO>}

Next question operator?

Operator

One moment. Our next question comes from Jason Kantor with RBC Capital Markets.

Q - Jason Kantor {BIO 1957973 <GO>}

Hi. Thanks for putting up a huge quarter. Can you give us some sense how you are thinking now that you have done this AMD launch, how you are thinking about the CRVO launch and how much of that is built into your guidance and how you are thinking about that relative to the rapid uptake in AMD?

A - Len Schleifer

Just a from the guidance, that is it should be viewed for the most part as our wet AMD guidance. Bob, do you want to comment about the launch of CRVO if we were to get it labeled this year?

A - Bob Terifay {BIO 4342122 <GO>}

CRVO is a much smaller market than the wet AMD market. It is about 30,000 patients in the United States have central retinal vein occlusion. The length of treatment of patients with CRVO could be much shorter. Some patients stop treatment at six months, although recent studies have shown that there are patients that will continue to benefit from anti-VEGF therapy for over a year. We see the CRVO opportunity as an opportunity to broaden the label to have the product more firmly established on formularies. Clearly the product will offer benefit to those patients who need it in CRVO but the real market opportunity will continue to be wet AMD.

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Q - Jason Kantor {BIO 1957973 <GO>}

Great.

A - Michael Aberman {BIO 6989908 <GO>}

Next question.

Operator

Our next question comes from Chris Raymond with Robert Baird.

Q - Chris Raymond {BIO 4690861 <GO>}

Thanks. Just another question on the launch, on the EYLEA launch. Just curious if you have any visibility into the dynamics of patients transitioning from the q.4 week dosing, the loading dose, to the q.8 week dose? I'm sure you know some have worried about sort of hitting a wall of sorts. Our checks kind of indicate that maybe that has already started and may be well under way. I wonder if you could maybe give some color as to what you are seeing?

A - Len Schleifer

Yes. We don't have patient level information on dosing. From surveys, what we hear is that the majority of docs use the three loading doses and then switch over to some less frequent regimen. Many will use the label, we hope, which is q.8 weeks but some continue to use on their own p.r.n. or treat and extend. Obviously, the more difficult patients that start who, for example, some who might not have been able to even get by with monthly dosing of their anti-VEGF, some of these patients may stay on monthly dosing of our drug which is, of course, also in our label.

A - Bob Terifay {BIO 4342122 <GO>}

I think some of our highest utilization, however, is in more rural areas where people have to travel far for their appointments and so the every eight week dosing is appealing in those types of the settings.

Q - Chris Raymond {BIO 4690861 <GO>}

Okay. Thanks.

Operator

Our next question comes from Jim Birchenough with BMO Capital.

Q - Jim Birchenough {BIO 5068439 <GO>}

Hi, guys. Just let me add my congrats on the quarter and the profitability. I wanted to drill down on the switch business and I'm just wondering if you have any metrics on what the switch opportunity is if you think about the type of patients that are being switched which the feedback we're getting is patients that have persistent fluid on monthly Lucentis and

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Avastin and if you think about what is the proportion of the market that could be switched and when you think about what has already been switched, I'm trying to get a sense of what is in front of us in terms of new switch. If you could maybe give us some detail on that?

A - Len Schleifer

Maybe I will ask George to comment on what is known from the data in terms of -- in some of the larger trials what fraction of people still have fluid at the end of treatment.

A - George Yancopoulos {BIO 1463723 <GO>}

It seems from the large studies that even with monthly Lucentis use, up to 30% to 40% of the patients do not achieve complete anatomical control and correction and the numbers actually from the catheter[ph] are even far higher for Avastin. It seems as if there are substantial proportion of the patients who might be able to benefit from a more potent anti-VEGF agent.

Q - Jim Birchenough {BIO 5068439 <GO>}

If I could -- can I follow up on that?

A - Len Schleifer

Go ahead, Jim.

Q - Jim Birchenough {BIO 5068439 <GO>}

I'm just try to understand these buckets, new naive, new switch, already switched and just get a sense of what's the new naive patient pool, what's the new switch patient pool and what's the already switched patient pool just so we can get a sense of what is in front of us in terms of growth opportunity?

A - George Yancopoulos {BIO 1463723 <GO>}

I can tell you that most surveys and most prescription audits will show that in any given month about 25% of eyes are new to anti-VEGF therapy, so 75% are continuing on anti-VEGF therapy. Is important that when we think about the switch market, there was a pent-up demand. There were a number of people who were coming in even more frequently than monthly due to edema and those patients were switched to EYLEA very, very quickly. So that's one of the reasons we are being cautious and not overestimating what the switch potential for the rest of the year is. We are encouraged by the switches we have seen, but there was a group of patients that were waiting for something new. We can tell you that of our switches, 60% of them came from Lucentis and, importantly, 40% of them came from Avastin. We anticipate to continue to see switches, we just did not know at what rate.

Q - Jim Birchenough {BIO 5068439 <GO>}

Okay. Thanks, guys.

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Operator

Our next question comes from Terence Flynn with Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the question. Congrats for me as well. Just wondering if you can comment at all on monthly trends, March relative to February, and then maybe anything in April relative to March that you are seeing. Because if I run through the numbers it seems like you saw a decent acceleration in March and I was wondering if there is anything that is driving that or if that is accurate? Thanks.

A - Len Schleifer

We're not able to comment on week to week, month to month or beyond the quarter trends. We have got to leave up, you will have to figure that one out by yourself. Even if we had data available for you today, the reliability early in the launch of all of this is you see fluctuations, and I don't want to comment on what we're actually seeing other than to say I think we have taken a pretty careful look and tried to model this in a number of different ways. We tried to take into account the switches, the dosing reductions, we've tried to take into account discontinuations, share of new patients, et cetera. You can build very complicated models or we can -- or you can try to make more simplified models but however we do it, we think that our guidance of \$500 million to \$550 million is the best that one can make with the data we have in hand.

Q - Terence Flynn {BIO 15030404 <GO>}

Okay. Thanks a lot.

Operator

Our next question comes from Steve Byrne with Bank of America.

Q - Steve Byrne {BIO 7019262 <GO>}

Hi. I think I will switch over to one of the development projects. Can you talk about why you think Sanofi would have elected not to co-develop 475 right ahead of the adcom[ph]?

A - Len Schleifer

I think that is probably a question that is better directed to Sanofi. I would not presume to speak for them.

Q - Steve Byrne {BIO 7019262 <GO>}

And the other two antibodies that you have in development that they've also elected not to co-develop, do you have plans to continue with those or is the data just somewhat underwhelming?

A - Len Schleifer

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None of the discontinuations, as far as I recall, have anything to do with a safety concern or certainly our view of the data. They have a very deep and broad pipeline. They are going to make decisions on what they want to develop and what they don't want to develop, what it fits into what they are up to. Nobody gets all of these decisions right. Obviously, I think Regeneron is in a strong enough position with its pipeline with more than 10 different things ongoing and multiple things going in the clinic each year that we certainly don't have to continue anything that George and his team feel don't make the cut either in terms of likelihood of technical success, safety concerns or market opportunity.

Q - Steve Byrne {BIO 7019262 <GO>}

Okay. Thank you.

Operator

Our next question comes from Biren Amin with Jefferies.

Q - Biren Amin {BIO 7512048 <GO>}

Yes, thanks for taking my question. Is your assessment that doctors are prescribing EYLEA in Medicare patients only with supplemental insurance and would co-pay assistance by the Company potentially help increase penetration in patients without supplemental insurance? Thanks.

A - Len Schleifer

Bob, you can comment on that but I will say at the outset that direct co-pay insurance to Medicare patients is something that we cannot do. Bob?

A - Bob Terifay {BIO 4342122 <GO>}

We have seen physicians use of the product in all market segments, Medicare without a supplement, Medicare with a supplement and we have seen significant commercial payer uptake. So, there are occasional delays in reimbursement. Often times paperwork is not filled out properly. There's also an ongoing glitch in the Medicare computer data base which delays payments, but we are seeing use across the board. In terms of co-pay, as Len pointed out, anyone that is on a government paid program, companies cannot provide direct co-pay assistance. We can refer those patients to foundations, independent foundations, who can help them. The Company does, for non-governmental patients in states where it is allowed, have a co-pay and assistance program and we have seen some use of that.

Operator

Our next question comes from Manny Mahinscher[ph] with Thinkequity.

Q - Manny Mahinscher

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Thank you for taking my question and congratulations again on the great quarter. So, I just wanted to drill down a little bit more on practices that are heavy users of Avastin. What sort of is your ongoing market research and feedback from your fee[ph] for suggesting in terms of physicians who are traditionally used to using more of Avastin. How are they viewing EYLEA now that it is in the market? Are you seeing a higher adoption in those practices as well? Thank you.

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A - Len Schleifer

Yes. The interesting thing is that the switch rate from switch patients is not -- it is less, that's 40% of our switches are Avastin and 60% are Lucentis, but it's not drastically less and especially because of the fact you would imagine that there are some people but not as many as you might have thought are on Avastin because of the financial inability to afford Lucentis or afford the co-pay. But there are many who are on it for other reasons, patient and doctor choices, and obviously we view those as a potential source for us to grow our market share as doctors get familiar with the product. I think we are seeing that. We are definitely seeing people who were primary Avastin users using switches and new patients with our product. But it is still early going and, as I said, our overall penetration in the entire market is only in the approximately 10% range. So we have lots of opportunity. But the Avastin market is clearly something, since it is the majority of the market, is clearly something we are focusing our attention on. Obviously, early on in the launch, as Bob told you on our last call, we focused on calling on the people who were using branded therapy and were higher users of Lucentis. And, as I said, we penetrated about 70% of those who are known to us but still now there's an opportunity to continue to push not only those but obviously the Avastin.

Q - Manny Mahinscher

Thank you. That's very helpful.

Operator

Our next question comes from Yaron Werber with Citigroup.

Q - Kumar Venkatesaran

Hi. Hello.

A - Len Schleifer

Yes, hi.

Q - Kumar Venkatesaran

Hi. This is Kumar Venkatesaran for Yaron Werber. Thank you for taking my question. Congratulations on a strong quarter. Earlier in the year you said that approximately 20,000 vials were shipped to the docs in the first five to six weeks of the quarter. Can you tell us what this number was in the last seven or eight weeks (inaudible)?

A - Len Schleifer

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We're not going to get into the -- I'm sorry, we're not going to get into the weekly or monthly or beginning of the quarter, end of the quarter shipments.

Q - Kumar Venkatesaran

Okay. Thank you.

A - Len Schleifer

You're welcome.

Operator

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

Q - Phil Nadeau {BIO 4838409 <GO>}

Good morning. Let me add my congratulations on a great quarter. Len, I was wondering if you could talk a little bit more about the market dynamics. Looking at what Lucentis posted which was more or less flat sales and then the big growth that you guys put out. It does seem like the market is growing and it is still kind of unclear where those patients are coming from. Were there patients who were off therapy because Avastin and Lucentis were not working for them or is it more rural patients who do not want to go in and invest in Lucentis who are now coming to use EYLEA? Could you talk a little bit about what is growing in the market so much?

A - Len Schleifer

Sure. Well, if you do the math, about a quarter of our sales came from people who have switched from Avastin so that would not show up as a loss of the sales from Lucentis and it reflects a growth of the market. Frankly, we really appreciate your surveys because we find them to be very constant with our surveys so they serve as a nice check. All of the work is still, I just to emphasize, your work, our work is still survey data and what doctors actually do, what they're going to do, what they did doesn't necessarily come through entirely accurately in these surveys so we caution everybody to just be careful with that. The most reliable information obviously is the sales number for the quarter that we have giving you.

Q - Phil Nadeau {BIO 4838409 <GO>}

Okay. Great. Thank you.

Operator

Our next question comes from Geoff Meacham with JPMorgan.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hi. This is actually Mike in for Jeff. Thanks for taking the question and congrats on a great quarter. I just had a quick question on EYLEA launch. I'm just wondering if you guys have a sense of what the discontinuation rate was in 1Q?

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A - Len Schleifer

I don't have that information available but I'm just guessing, Frank out guessing that it is pretty low because people usually try it for several months before they make a continuation or discontinuation decision. That is just a guess.

Q - Geoff Meacham {BIO 21252662 <GO>}

Got it. And then if I can ask a quick followup. Just curious what percentage of docs have been formally reimbursed so far in 1Q?

A - Len Schleifer

I do not have information available.

Q - Geoff Meacham {BIO 21252662 <GO>}

Great. Thanks.

Operator

Our next question comes from Jim Birchenough[ph] of BMO Capital Markets.

Q - Jim Birchenough {BIO 5068439 <GO>}

Hi, guys. Just two quick ones, I guess. You mentioned 10% share of anti-VEGF therapy. What is your share of VEGF naive patients and then the second part I was wondering if you can give us an update on timelines for the DME Phase 3 trials?

A - Len Schleifer

Right. Remember, this is survey responses, it is about the same. The 10% is about the same of new patients as well as treatment experienced patients, is that correct, Bob?

A - Bob Terifay {BIO 4342122 <GO>}

Yes, that is correct.

A - Len Schleifer

That is survey data. As far as DME, that is going along very nicely. As I said, our first -- as I said in the past, our first study is already enrolled, our US study and our ex-US study, I do not have the latest update but if it's not a completely enrolled, it is all but enrolled at this point.

Q - Jim Birchenough {BIO 5068439 <GO>}

Just as a followup, do you guys have any insight into what the implications of the recent MEDCAC meeting might be for reimbursement for the category? And whether there might be some prospect for EYLEA reimbursement in DME in advance of data? I know you can't promote to it, but insights on the MEDCAC panel?

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A - Len Schleifer

I will turn it over to Bob to give a little bit of background on this MEDCAC meeting and what implications he thinks it could have for reimbursement.

A - Bob Terifay {BIO 4342122 <GO>}

First of all, as you pointed out, even if reimbursement was offered, we would not be able to -- would not promote EYLEA for DME until we got FDA approval of the indication. The MEDCAC sort of left things with uncertainty. They went back and they're going to continue to examine the possibilities. There was no clear-cut decision so right now the individual carriers are making decisions as to what they reimburse or don't reimburse in DME. From everything we hear, this is probably going to be continued discussions and no firm conclusions for quite a while.

Q - Jim Birchenough {BIO 5068439 <GO>}

Have you seen any carrier decisions where they have include EYLEA reimbursement in DME?

A - Bob Terifay {BIO 4342122 <GO>}

At the present time, EYLEA is reimbursed by carriers for AMD only.

A - Michael Aberman {BIO 6989908 <GO>}

Jim, we're going to move on and, Operator, we'll take one last question.

A - Len Schleifer

We have run over already.

Operator

Our last question comes from Manny Mahinscher with Thinkequity.

Q - Manny Mahinscher

Hi. Thanks for much for taking a followup question. Maybe just switching gears here and talking about ARCALYST heading into the panel on May 8. What are your expectations going into the panel in terms of outcomes and in terms of what happened with Canakinumab completely acknowledging that it is not an apples to apples comparison but just wanted to get your preparedness?

A - Len Schleifer

Right, I think you would be inappropriate at best to lay down our expectations of how a panel is going to act. That is really their business. I know that George and the team are working hard to prepare for this and we think we have a strong package and we think our package is distinguished both in its indication as well as the contents of our package

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compared to Canakinumab, but I think that advisory committee is coming up in a little over a week so we will get to see pretty soon.

A - Michael Aberman {BIO 6989908 <GO>}

Thank you, Operator, and thank you, everyone, for participating in today's call. As mentioned earlier, myself and some others from the investor relations team will be available for follow up calls if you have any further questions.

Operator

Ladies and gentlemen, this does conclude today's presentation. You may disconnect. Have a wonderful day.

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