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EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at Leerink Partners Global Biopharma Conference

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OVERVIEW:

Company Summary

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CONFERENCE CALL PARTICIPANTS

David Reed Risinger Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

PRESENTATION

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

All right. So I am pleased to introduce our next session with Regeneron. My name is Dave Risinger. I cover diversified biopharmaceuticals. And it's very much my pleasure to welcome the company's new CFO, Chris Fenimore; and Senior Vice President of Investor Relations, Ryan Crowe. Obviously, Chris has been with the company a long time, but just formally took on the role earlier this year. So thanks very much for being with us here today. I thought we could just start with the EYLEA franchise if okay, we'll just jump right into it. So...

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Actually, David, if I could just...

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Oh, I'm sorry.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Forward-looking statement briefly. I'd like to remind you that our remarks made today may include forward-looking statements about Regeneron. Each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements. A description of material risks and uncertainties can be found in Regeneron's SEC filings. Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Now that's out of the way, EYLEA.

QUESTIONS AND ANSWERS

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

All right. Thank you. So I guess just to kick off, could you just comment on physician feedback so far on EYLEA HD and just frame the switching? So what you're seeing in terms of from other products to HD and from EYLEA 2 milligrams to HD? If you could just provide the latest on that, that would be helpful.

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. So let's just start with EYLEA performance for the fourth quarter last year. As everybody is aware, the product in its first full quarter on the market did $123 million in net sales. If you look at share of the category, the EYLEA franchise in total between 2 milligram as well as EYLEA HD did

about 49% and indicative of the strength of the franchise. In terms of physician feedback, it's been overall very positive from what we've been hearing from our colleagues out in the field. And one thing that we announced yesterday is that we surpassed recently 100,000 orders shipped of EYLEA HD, and that's an important milestone for physicians in terms of getting comfortable with the safety of the product. There has been experience in other ophthalmic launches recently, where physicians have just been concerned about things like intraocular inflammation and just want to ensure that hitting that milestone gets them comfortable in terms of prescribing confidence.

In terms of switches, we see that it models what you see out there in the marketplace in terms of how the therapeutics are prescribed. The predominant number of switches are coming from EYLEA 2 milligrams to HD, but we have seen switches from other branded agents as well as Avastin, and we get a nominal at this point, although growing, portion of naive patients as well.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Got it. And just in terms of those switches, obviously, you still probably have some samples or effectively free product in the market. Could you just talk about how much that constrains the booking of net revenues currently and how that will evolve in the future?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Sure. Thanks. And Dave, thanks for having us at the conference. Really appreciate the opportunity to present here. I'd say on samples, it's pretty typical for any pharmaceutical launch to allow for a risk-free trial of a product, and we don't view it as something that's holding back revenues, but rather something that's helping us build a market through experience. So we have an active sampling program. It's an on-demand program, so it's not as if we're going to retinal practices and dropping off a heap of samples. It's made to order -- or an order is placed in that it's fulfilled. So natural part of every launch, I think, as the launch progresses, it will naturally taper, and that's sort of the direction it's headed right now.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

And maybe this is too direct question, but why provide any samples after the permanent J code is issued April 1st?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

We just want to make sure that they're available. I don't -- we're not, like I said, proactively dropping them. We're making them available via the order, and we'll see how active the program is post the J code.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Got it. Okay. Thank you. And speaking of the J code, how important of an inflection is that? I mean obviously, the uptake is already very strong. It doesn't seem like physicians are really hesitating, but I don't have a good sense for it.

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

So the permanent J code is effective April 1st. It's very, very important. We hear there are a certain subset of physicians that do have or want to have reimbursement confidence. So they either have in limited cases used EYLEA HD or there are certain physicians maybe that haven't written any scripts yet because of that reimbursement confidence. So we definitely believe it will be very important and vital the success and the continuation of the launch.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Excellent. Very helpful. And there was a publication recently that did raise some questions. So the recent New England Journal of Medicine companion editorial to the 48-week PHOTON results in The Lancet seem to call for additional validation of EYLEA HD. Could you discuss that editorial's concerns and comment, please?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Yes. I mean, there was, I think, a critique that we understand. What I think has since the publication of -- we haven't published the 96-week data, but we've presented the 96-week data. And I think, I don't know, if those people that wrote the editorial are waiting for a peer-reviewed journal, and will discount anything at a medical meeting. But obviously, the results that we presented in the 2-year data, I think, fully support the clinical profile in the 48-week data set that was in the subject of this editorial.

One of the other critiques was that the EYLEA arm was capped at every 8 weeks, and we should see what it can do if it wasn't capped. Our response to that is there's other protocols, including protocol T that looked at EYLEA versus Avastin in an uncapped manner. And the median number of injections was the same in the year, the first year of the study. So I don't think -- I think we designed the study appropriately. I think the results speak for themselves and the feedback from the real-world prescribing experience has been very positive.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Excellent. So why don't we get to DUPIXENT before we go into more of the financials for the company. So, how are you characterizing your expectations for the potential uptake? I know that Sanofi is a partner there and often makes commentary as well. But, how rapidly might the COPD adoption occur?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

So if you look at COPD, we've got a PDUFA date of June 27, so it's coming up pretty quickly. We and our partners, Sanofi, as we look at the market opportunity, there's about 300,000 Type 2 COPD patients in the U.S. I think if you look at the G7 in totality, that number is about 550,000 patients. So a large market opportunity. There hasn't been a lot of innovation in this space. There are no biologics. And I think the last time there was any therapeutic, sort of, brought to market was probably over a decade ago. So we think there's a large opportunity there. I don't know, Ryan, if we can speak to anything about uptake in your perspective.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

I think it's -- it will be a first approved biologic in COPD. There's a lot of patients out there around 300,000 in the U.S. There's a lot of, I guess, enthusiasm from the KOLs about having something for patients that are not well controlled on maximal inhaled triple therapy. So we're very excited to be hopefully bringing this to market around the middle part of the year, pending FDA approval. And I think the launch has an opportunity to be a strong one.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Excellent. And then obviously, it's not your responsibility to comment, but I'll ask you anyway. So with respect to Tezspire, there's a Phase II readout coming. How do you see that as a competitive threat? And how are you commenting on that, please?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Well, we're certainly watching and waiting as everyone else is. I know the data from their Phase II program in COPD is imminent. I think they're looking at a slightly different population, one in which some patients have elevated eosinophils at baseline, while others do not. They're also looking at current and former smokers as DUPIXENT did. I think it will be important to see what the overall rate of exacerbation reduction is. I think the bar has been meaningfully raised by DUPIXENT and whether or not Tezspire can now meet, kind of, a low 30s percentage reduction will be a challenge, but we'll see what the drug does once the data comes hopefully very soon.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Okay. Very good. And then turning to CSU. Could you just comment on that opportunity, how you see it really in the wake or context of FDA's initial rejection last year?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

So yes, we received the CRL in October of 2023. The FDA was seeking additional evidence of efficacy. We had one study that was in biologic-naive patients that read out positively. And then we had a study in omalizumab-experienced patients that was negative and stopped for futility at an interim analysis. So we had already begun a study C that replicated the biologic-naive study A. And so that was already enrolling. I believe we should have data for that study in the fourth quarter and assuming the results are replicated, we would then resubmit our sBLA for this indication, and hopefully, could be on track for an FDA decision in the first half of '25.

The opportunity is attractive. I mean, XOLAIR is, I think, the lead indication there or the leader in that particular indication. And we think that a lot of patients go to dermatologists for atopic derm and sometimes have CSU as well, but they don't typically prescribe XOLAIR, allergists do. So we think this is an opportunity to bring the specialties together a little bit and maximize the opportunity. I believe in the U.S., there's around 300,000 patients. So it's a very big pool of patients.

But I'd say also this is not necessarily a chronically treated disease. It's sometimes more sporadically treated, treated when there are flare-ups. So perhaps, while a big population, the durability of a script may not be as long as something like a COPD, which has a similar size patient opportunity.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Okay. That's very helpful context. So Chris, I think it would be helpful for you to just frame Regeneron's financial prospects at a high level. The company has had a tremendous performance in the past and you get to carry the fortune and run with it here. But how do you see the company's outlook?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

So as you know, Dave, we don't give any long-term guidance in terms of operating margins or gross margins or anything like that. We're obviously very excited about the prospects of the top line growth with continued growth from our DUPIXENT alliance with Sanofi as well as, obviously, the ophthalmology franchise. If you look at the expense side, just to give a little bit of qualitative color on cost of goods sold, we gave non-GAAP gross margin guidance of between 89% and 91% of net product sales. If you look at that number, embedded in that number is, we are building a manufacturing plant for fill-finish capabilities, and the start-up costs associated with that facility are impacting the margins a little bit in 2024. But as that facility ramps up in 2024 and gets fully implemented, we would expect those costs to be capitalized and sold through as product costs in the future.

In terms of R&D expenses, we gave guidance this year. It was about 12% year-over-year growth. If you look at the midpoint, and that's just reflective of -- we have a lot of opportunities in the portfolio. The pipeline is advancing into later-stage studies. So if you look at the likes of fianlimab or hematology products advancing into Phase IIIs as well as our partnerships with Intellia and Alnylam on the genetics medicine space. And then we

have also said publicly that we hope to bring up 10 new INDs into the clinic in 2024. So there's plenty of opportunity for us to obviously invest in the R&D engine, and we think that's the best avenue to provide future revenue growth and return value to shareholders.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Excellent. And then with respect to the Sanofi R&D bookings on the income statement, could you just remind us about that balance and how that could evolve over the course of time? And how much of a positive inflection the company might end up experiencing down the line?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. So the original way the Sanofi collaboration was structured in terms of funding R&D expenses as Sanofi was responsible, depending on the type of studies and where the different programs were in their development, somewhere between 80% and 100% of the development expenses upfront. We then would be obligated to repay that delta so that we ultimately would have paid 50% of those expenses, but we paid back out of this concept called a development balance. We've been paying that development balance back over time. Originally, we were repaying 10% out of our share of profits towards repayment of that development balance. In the middle of 2022, we amended our agreement with Sanofi to increase that from 10% to 20%.

So we're going to see an acceleration, we have seen an acceleration of that repayment. The balance as of the end of December was $2.3 billion. It was a reduction in that balance of $534 million over the course of 2023. We haven't given any specific guidance as to when we exactly expect that to be paid down, but we think over the next several years that, that balance will ultimately be paid down.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

And so that paydown is obviously growing right now, because you're growing the R&D spending, and then it will drop to 0 at some point once it's paid off.

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Correct.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Got it. Okay. Very good. And in terms of investments in the out years in R&D, once again, you don't provide guidance. But how should we think about the rate of R&D spending growth that's required to fuel such a significant pipeline? You're already investing aggressively, but you're going to have to continue to invest more and more. So how do you think about that at a high level?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

So again, we don't give any long-term guidance in terms of specifics on where the R&D spending will go. I will tell you that we invest with a rigorous process. The management team gets together and decides what the appropriate size of the investment is based on a number of qualitative factors, such as: what do we think the probability of success is, what do we think the investment will be that will be required, what do we think the market opportunity is, what do we think the competition looks like in terms of balancing where we decide to invest our capital on the R&D front.

I can also add that while we're investing in a lot of these programs, a lot of the programs take time... So the investment is obviously not all upfront and a spread over a number of years. And then things cycle on and off. So programs that are now in Phase II will eventually progress to Phase III

and those that are currently in Phase III ultimately get wound down and ultimately result in commercialization. So that's kind of the way we think about it. And obviously, as we model out our long-term sort of prospects and things like that.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Got it. So I wanted to pivot to linvoseltamab. It's an exceptional profile. You've laid that out. I think the competitors have heard that, Pfizer and J&J, and they've said, "Well, that's great, but we're still going to dominate because we're bigger, and we're earlier, and we're better commercially." So maybe you could just comment on how you plan to, I guess, win over the market, considering that if all 3 products were launched today at the exact same pricing and access, I think linvoseltamab would totally dominate. But I just don't know how to think about it. And I'm sure Len is driving the commercial team to rev up here, but it would be helpful to get your perspective.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Yes. We're -- obviously, J&J and Pfizer are very strong in the oncology space and in the hematology/oncology space. So we're very respectful of the success that they've had with other products. But to your point, I think the efficacy profile that we hope to get into the label for linvoseltamab upon its August approval, hopefully, we're talking about 70-plus percent response rate and a 46% complete response rate after 11 months of follow-up, which compares favorably against those other BCMAxCD3 antibodies from J&J and from Pfizer, who have, I believe, complete response rates in the upper 20s with similar follow-up.

So again, most important for patients is what's going to work best for me. And data ultimately will sell your product. We're firm believers in that. And I think our commercial sales force will go in with a pretty strong arsenal of data points to allow doctors to make that decision. And I am very confident in the team's ability to win in this market, and ultimately move linvoseltamab up in the treatment paradigm and open up even larger commercial opportunities.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

That's helpful. And is there any upcoming data to watch at AACR that we should focus on for linvoseltamab?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

I think it's more incremental. There might be some more data on additional follow-up, but I don't think it's going to be a meaningful new data set there.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Okay. All right. Great. So maybe we could pivot to obesity. And I guess, talk about the Regeneron approaches and sort of what to watch over the next year or 2?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Sure. I'm impressed you made at 23 minutes in before we started talking about obesity. No, obviously, we are very excited about an opportunity to potentially participate in this massive commercial opportunity. And the incretin-based therapies have shown that they can meaningfully improve health outcomes, which is extremely important for society. One of the drawbacks though, of these therapies is that of the weight that's lost, anywhere between 20% and 40% is in lean muscle mass, and where we think we can play is in helping to either reduce or eliminate the loss of lean mass, which would, we think, even further improve these health outcomes.

So, probably most important to us is adding on top of -- so we have a Phase II study we're about to initiate probably middle part of this year that will combine semaglutide per label with 1 or 2 of our muscle preservation antibodies. One is a GDF8 antibody, myostatin, it's called trevogrumab, and the other is an activin A antibody called garetosmab. And these are antibodies that bind to the ligand, which is a slightly different approach than we see with Versanis at Lilly and bimagrumab program, and others that are in the similar cascade. We think having this very precise targeting of the ligand will reduce off-target toxicities. And we, in fact, have a pretty fulsome safety database for trevogrumab already. It's been dosed in over 400 patients across healthy volunteers and other, sarcopenic, patients in earlier studies.

So we have a very -- we're very confident in the safety profile for anti-myostatin and over the course of this Phase II study, over 26 weeks, we're going to look at semaglutide, plus trevogrumab, plus or minus, garetosmab and after 26 weeks, evaluate overall weight loss as well as overall fat loss.

The second part of this study will look at the maintenance phase, where semaglutide will be dropped and roughly half of the patients will be on placebo. The other half will remain on high-dose trevogrumab, the anti-myostatin antibody, to see if weight maintenance is better maintained in the presence of trevogrumab or not. So we're very excited. We think we can potentially make these incretin-based therapies better, and again, lead to a better overall health outcomes.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Very helpful. And so, historically, muscle-enhancing therapies have failed either due to safety issues or because they don't improve functional muscle. And so, obviously, you've commented on the safety, given your ligand approach. But is there any plan to assess the functionality of muscle? And if so, what have you disclosed how you will do so, stair test, or grip test or anything like that?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Yes. I mean I think functional muscle is important. But I think for us, overall, preserving lean mass should preserve the metabolic rate. As you're losing lean muscle mass you are lowering your metabolic rate, and that is allowing for the weight regain once you discontinue a therapy to accelerate. So by preserving muscle, we hope to preserve the metabolic rate.

In terms of the muscle functionality, I think we do have some qualitative endpoints in our Phase II study to look at questionnaires about how people can do day-to-day tasks. And then there's even in some exploratory endpoints, a sit-stand test, where somebody's ability to stand up and sit down is going to be looked at. So we're already beginning to explore that. And based on the proof-of-concept results, that will probably inform what we do next in terms of measuring functional muscle.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Got it. Okay. And then could you just talk about the other obesity programs as well?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - SVP of IR & Strategic Analysis

Yes, briefly, we only a couple of minutes left, and we've got a lot to get through now. But we have a leptin receptor agonist antibody that we hope to initiate a Phase II study with an incretin-based therapy later this year. And that is one that we want to look at whether or not it can augment weight loss and/or improve the maintenance of weight that's lost while on this incretin-based therapy. And then we have a genetic discovery from the Regeneron Genetics Center that we've been trying to target in various ways, called GPR75.

So, we have a small molecule collaboration with AstraZeneca that we are still in the kind of the screening phase of various molecules. We are looking at how to target that with an antibody internally. And we're also looking at an siRNA with Alnylam to try and target it. And recently, we put out some very early mouse data that have shown that by knocking out that gene even when feeding mice, a high-fat diet, those that have the gene knocked

out aren't gaining the weight while others are. We think the gene could be related to activity levels. So we're excited to move that forward with additional mouse study and then hopefully nonhuman primates next.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Great. Well, why don't we conclude just with you, Chris, on thinking about the company's financial strength, capital allocation, et cetera. So could you just remind us about where your balance sheet stands, and how the company is evaluating the possibility of potentially initiating a dividend in the future?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Sure. So we finished the fourth quarter with about $16 billion in cash, about $2.7 billion in debt. So we obviously have a very healthy balance sheet. In terms of capital allocation, and this is consistent with what we've communicated in the past under Bob's tenure, is , first and foremost, it's investing in the R&D engine and the capabilities of George and his team, and we will continue to do that. We're very active on the business development front. We're constantly -- we have a robust BD team that's always looking at various opportunities. We'll continue to do several deals a year on the partnership collaboration front, where we identify companies that have complementary technologies to what it is that we're doing where we think there's some synergies between what each party is doing.

Historically, most recently, we've done a few, what I would say, relatively modest acquisitions. We did Decibel therapeutics. We basically also recently announced 2seventy; we acquired their early-stage R&D programs, while they kept their commercial asset. We don't feel compelled to do any M&A, and we'll be fairly selective based on what we feel we have going internally. But if the right deal presented itself, we would obviously look at it and if it made sense, we think we have the flexibility to do something where we don't feel compelled to do anything.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

And any comment on dividends?

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

So we did an analysis last year. We actually brought in some outside firms to help guide us in the process and just make sure we're thinking about things properly. The decision at that point was -- it wasn't the right time then. We didn't rule out doing something in the future. We'll continue to evaluate it. As we talked about the development balance at some point, that will be paid off, and that might be an inflection point where we might start to think about things differently. But obviously, we'll have to look at it at that point in time and then make that decision.

David Reed Risinger - Leerink Partners LLC, Research Division - Senior MD & Senior Research Analyst

Got it. Well, Lilly stock has shown us that paying a dividend doesn't necessarily hold back your multiple. So we'll look forward to future updates on that. So, thanks so much for taking the time. I appreciate you being here. Thank you.

Christopher R. Fenimore - Regeneron Pharmaceuticals, Inc. - Senior VP of Finance & CFO

Thank you, Dave.

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