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OVERVIEW:

Company Summary

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Ryan Crowe Regeneron Pharmaceuticals, Inc. - VP of IR

CONFERENCE CALL PARTICIPANTS

Christopher Joseph Raymond Piper Sandler & Co., Research Division - MD & Senior Research Analyst

PRESENTATION

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Okay. I think we're going to go ahead and get started. Thanks, everybody, for being here. My name is Chris Raymond, I'm one of the biotech analysts here at Piper Sandler. Welcome the 35th Annual Piper Sandler Healthcare Conference. It's my pleasure to introduce our keynote company for today, Regeneron Pharmaceuticals.

Joining us, we have Regeneron's CFO, Bob Landry; along with Ryan Crowe, who heads up the Investor Relations effort at Regeneron. So just some logistical housekeeping issues maybe to cover first. I wanted to thank, however, Bob, for being here. I think this is likely your last investor conference before you formally work on your pickle ball game and golf game and anything else you want to do.

Well deserved and really enjoyed working with you the last several years here. Maybe just to go over the format, we'll have a couple of minutes of introduction from Regeneron's forward-looking statements, et cetera, and then we'll go into a fireside chat format with more format Q&A. We want to make this as informal as possible. So if you guys have any questions, raise your hand. I'll make sure it gets asked. If you don't want to do that, just e-mail me, I'll be checking my phone here as we go along.

So maybe first, Ryan, if you want to start with the forward-looking statements and then a quick introduction.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks for having us. Chris, 35th annual, 35 years Regeneron has been in business. It was founded in 1988 as well. So thanks for having us. Always great to be here. I'll just do this forward-looking statement, and we'll get started. I'd like to remind you that remarks made today may include forward-looking statements about Regeneron and 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. Bob?

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

Great. Chris, thank you for that warm introduction and happy that it's with you as my last kind of stage appearance. So two minute-kind of recap just to reset everybody had earnings kind of first week of November, and we were very, very pleased with earnings. So we had a 15% top line growth on net revenue, we had 4% EPS growth. On the bottom line, we did have a $100 million IPR&D charge as a result of a payment we made to Alnylam with the success of our ALN-APP drug that's in Phase I and if you exclude that, I think we were up 11% with regards to EPS growth, all good.

High dose EYLEA got launched in the third week of August. I know there was a lot of attention paid to that, and we were pleased with the $43 million that we've registered within the kind of the first 6 weeks, that bodes very well for the drug, and it's off to a great start. I'm assuming we'll talk a little bit about that today.

Also in the third quarter, we had good PULSAR data with regards to wet AMD. That's our 2-year study that showed how good this drug is really going to be in the VEGF category. We had big news yesterday, if you were paying attention. We got DUPIXENT COPD interim Analysis in which we are hastily with Sanofi going to file an sBLA by the end of the year.

And again, this is an accelerated approach. As you know, we took an interim peak and all things were positive on that. In fact, the BOREAS trial was -- with regards to exacerbations the data was really fantastic. So this is going to be our sixth indication with DUPIXENT. So the teams are working hard to get that filed by the end of the year.

We have EoE, peds PDUFA date, end of January, again, just kind of another layer on the DUPIXENT story, all good on that front. With regards to Hem Onc, so we are going to become a Hem Onc player, and it's going to start with a PDUFA date with regards to our CD20, CD3 in lymphoma diseases, and that's going to be March 31. So again, something to pay attention to.

And the team back in Tarrytown is working hard to make sure the filing for our BCMA drug is going to be in place by the end of the year. Again, that's exciting. We're hoping for that to be kind of a late summer launch in Hem Onc. So again, a lot of things happening at Tarrytown. We're very pleased with how things are going.

Okay. Chris, with that.

QUESTIONS AND ANSWERS

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Yes. So with all the activity, I've got about 2 hours worth of questions. I'm going to try to boil it down to 15 minutes here. So let's maybe just jump in. So maybe some CFO questions, if we can start with that. So maybe just on the leverage, just noting the Sanofi collaboration begins to provide significantly more P&L leverage once you guys repay your R&D obligations. I know you've talked about this, you signaled this pretty strongly to the Street. But by our reckoning in our model anyway, this begins in 2026, I think you guys noted or you noted, Bob, on your last quarterly call that, that obligation is now just $2.5 billion. In your view, does the Street fully understand the magnitude of this benefit, in terms of what it means to your P&L?

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

Chris, I think they're coming around. I think analysts are beginning to do a good job with regards to capturing this. And again, to put a little background on what Chris is talking about, we have an off-balance sheet liability of $2.5 billion that has accumulated over time. With regards to the development of DUPIXENT and Praluent and Kevzara and itepekimab, in which we were in a 50-50 relationship, but we haven't been funding on a 50-50 basis. As a result of that, a development balance off balance sheet kind of builds up and it's at $2.5 billion, and it was roughly, let's say, $2.865 billion as we started the year.

And we're continuing to pay this down. And we're paying it down based upon a percentage of the profits that we earn on DUPIXENT each quarter. Now what Chris is referencing is eventually this will be paid off, and it will be a significant inflection to our earnings, to our margins when that time comes. As you heard Chris say, he's got 2026. Our last qualitative comment was basically in the next few years. Certainly, with the data coming from BOREAS, the COPD trial, if we can get that to market sooner, given the patients and the patient count within the COPD indication, we hope for that to be as soon as possible.

So Chris, I do think people are coming around on it, and that is a big earnings inflection point for Regeneron when we no longer have to pay. And by the time at the end of that transaction, we could be paying somewhere between, I don't know, $600 million to $800 million to Sanofi on it. And again, that will kind of magically go away once that balance is paid off and that profit will drop to the bottom line. So again, important to have that in your models going forward.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

So there's another question. I know you guys get a lot. And I'm going to try to ask it in a novel way. But on capital allocation, you guys ended the quarter -- third quarter with $13 billion, I think net cash of $13 billion. You're throwing off $1 billion plus per quarter. That's arguably accelerating, at least, by our math. We have the business amassing some $28 billion or so in cash by 2026, unless something dramatic changes. So again, I know you get this question all the time, and I've heard your answer. It's pretty consistent that you guys invest in R&D, and you've done a lot of very consistent deals, I think, in terms of stuff that did complements, the science focus of the company, which is all great.

But maybe more pointedly, as I've seen Regeneron evolve in your tenure, Bob. You guys have gone from Regeneron does not provide guidance to, you guys do provide now, some guideposts anyway. Stock-bought repurchases were not a thing and now that's clearly a part of your plan. Even with a steady state of tuck-in deals, you're going to have this enormous cash benefit potentially, again, unless something dramatic changes. But at what point, I guess, does it make sense to start talking about a dividend?

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

Yes, Chris, thanks. And we do get that question a lot and I mean we are in a super envious position with regards to the strength of our balance sheet and the optionality it provides. Our job as kind of CFO and the management team is to make sure that we use it correctly. We've gotten a lot of kind of questions recently from our largest shareholders with regards to dividends.

And again, these are shareholders that have kind of a fund of funds with regards to many funds under their umbrella, and they would love to open up Regeneron to more than just kind of growth funds or non dividend-paying funds. So that's where the pressure has come. So we took it upon ourselves to do a super deep dive beginning in the summer, between the IR Department and the Treasury Department and we brought in kind of 3 investment banks to kind of get their feeling with regards to what the timing is on this. And we use Amgen and Gilead as kind of analogs. We did all this work. Again, I talked about this development balance inflection coming in the next few years, and the decision was not right now with regards to dividends.

I find it hard to kind of launch a dividend program when yields are at kind of north of 5% when you probably can't give anything more than 50 bps or 75 bps, but that will be for a later day. So it's kind of on the horizon. The new CFO, in determination with the Board, and the CEO, Len Schleifer, they'll make a determination on when timing is appropriate. But again, we aren't getting a lot of pressure on that front and I personally think that it's probably in the foreseeable future in which Regeneron will become a dividend-paying stock.

And again, to what Chris said on capital allocation, not to make any kind of new news on my last kind of stage appearance we are going to continue to invest in R&D. We're going to drive that hard. We got 36 assets in the clinic. We have more and more INDs being put forth kind of every year. BD will continue to do tuck-in deals. Tuck-in deals make it a little bigger than what we've been doing with regards to Checkmate, and Decibel.

And then buybacks. We've been kind of riding buybacks pretty hard. I think since our launch in November of 2019, we bought back $11.7 billion of stock. We did it at a handle of $555.00/share. We're pretty scientific. We do a lot of intrinsic valuation with regards to where we are buyers as compared to what the stock price is. So again, that's played pretty favorably, and you'll continue to see that coming out of our repertoire going forward.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Excellent. Okay. So let's maybe jump into some of the commercial push-pull sort of dynamic. So maybe on EYLEA and the ophthalmology business. So you guys had a really nice initial print for the 8 milligram, the high-dose format for EYLEA and I know you guys haven't wanted to give a ton of color in terms of patients, the source of patients or sampling efforts. I know [Marion McCourt] did mention that some of the patients in that initial print for the HD format came from Avastin.

Some from our Vabysmo and so and others. But it's just -- from our survey work, at least, it seems that it's not a one-for-one sort of switch. It's not just a cannibalization and you're going to switch out all the EYLEA patients for the EYLEA HD, that there's a net gain for the franchise. I've spent the last couple of days getting calls from investors who are needling me for my Street-high estimates for this franchise.

And noticing actually through some of those conversations that there's a huge variance in terms of what people are modeling. And again, I know you guys don't give revenue guidance, but that seems to be -- especially in 2024, like we're talking $2.5 billion or so from high to low. At some point, does it make sense to provide, at least, some sort of guard rails, at least, for folks especially as you -- this important conversion of the market?

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

Yes, Chris, as we approach year-end, I mean, we'll see where the models are. It's probably unlikely that we're going to do that. Again, I'll leave that to the new CFO, working with Dr. Schleifer in terms of what the approach would be. I mean, it will be our job to make sure that we kind of message where this is going. We may not give kind of exact figures. But again, we don't want it to be so asymmetric with regards to where things are going to play out. And with regards to high dose, we think it's off to a great start.

So thanks, Chris, for saying how good the print was. And again, we're getting patients from kind of all over. We're getting kind of switches, naïve patients and recalcitrant patients, which is good, and it's coming in both wet AMD and DME, the two big indications there. And as you can expect, Ryan and I, we kind of put our ears to the ground. What are we hearing from physicians? And we're at the stage now that we're having a lot of patients come back for kind of dose #2 and dose #3.

We're hearing really good case studies about how physicians are having their recalcitrant patients come back, ones that they could never get dry and probably those that were the frequent flyers, and they're seeing dryness for the first time, which is really kind of fantastic news. And I think that bodes well for kind of the future of the franchise.

And Chris, to your point, I talked about our buybacks. It's done on our intrinsic valuation. And I will tell you, and I got asked this question yesterday by someone, "Where is the greatest separation between my intrinsic valuation and where the Street is?" And I would say it's the EYLEA franchise without getting into specifics. I mean, we do not have the declines that we see within the franchise that's coming out of the sell side reports that are there. Most of the sell side.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

All right. So cool. Maybe one more sort of EYLEA ophthalmology question. So we've seen a lot of players sort of come and go. We've seen gene therapy approaches, sustained delivery of TKIs, a bunch of different modalities. To be fair, there's still a few standing sustained delivery TKIs that are out there. But when you guys think about the landscape competitively, when you think about maybe 5 years from now. Is there any modality that you view, it could be a game changer that has maybe George up all night, worrying about it?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

I think George stays up all night worrying about a lot. But I don't think that we see anything really on the across the spectrum of ophthalmology and retinal disease therapies that is going to disrupt the current treatment landscape, which is focused on anti-VEGF. We certainly keep our eyes on all of our competitors and all these competing modalities in gene therapy is in implantables and sustained delivery.

And I think our view is EYLEA HD addressed the primary unmet need in the space, which was duration. Bob mentioned the PULSAR study. And the second year, by the end of the second year, almost half, 47% of patients were eligible for every 20 week or every 24-week dosing. That's pretty good. When you're down to 2 or 3 injections per year, and I think doctors are going to want to see their patients, at least, a couple of times a year to ensure that vision is not being lost, that they're not seeing fluid reaccumulate.

So I think the unmet need has been met with EYLEA HD, in large part. I'm interested to see how some of the science works out with some of these other modalities and mechanisms. But again, I think we've seen some implantables that have gone -- that have tipped over. And I'm thinking of Susvimo, but we'll see how the others work out. To me though, I think we're very comfortable with where EYLEA HD sits currently and in the future for retinal disease treatments.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Okay. So one more ophthalmology question, and this is a topic that I'm actually kind of surprised it doesn't get more airtime. You guys alluded to this and talk about it. It's your geographic atrophy program, and for folks who might not be aware of this, I know you guys talk about pozelimab and cemdisiran as a combo, IV combo in geographic atrophy.

I think, Ryan, you've articulated a plan to potentially be able to start a Phase III or a Phase II/III trial early next year. This kind of intrigues me without really any human data. What is -- first one, the communication plan, I guess, of this, in terms of what data you have that supports jumping into a later-stage trial, like that in such a time -- such a fashion of timing and maybe just give a preview of what you -- how you plan to talk about this program.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Yes, it's very interesting, and I think we have some good tools to potentially address this disease, which the exact cause is not even really known, but it's believed it be complement mediated, and the current therapies that have been recently approved by the FDA, they look to regulate complement in the eye with either C3 or C5 inhibitors. Our approach is going to be different.

And it's going to be a systemic delivery, but it's going to be and every 4-week subcutaneous self-administered injection. So we are not looking to put any needles in eyeballs. This will be a self-injection every month. And the data that we've accumulated is in a PNH population where we've seen rapid complete, uninterrupted knockdown of C5. And the siRNA component of the combination kind of stops the manufacturing of C5 protein in liver, where the majority of it is synthesized. And the antibody piece knocks out the circulating C5. So we hope to share that data very soon.

I think everyone will kind of say, "Wow, that's an impressive knockdown and we compared it against ravulizumab." And that's kind of considered the standard of care today for C5 inhibitors. And so we're looking forward to sharing that. And I think once people see that data, they'll understand our excitement around potentially developing a geographic atrophy asset, but also about the combination of other siRNAs and other antibodies for other disease types. So it really could open up a whole new flank for approaching different diseases that are currently -- have high unmet need.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Excellent. Okay. Let's pivot in the 1.5 minutes we have left to Dupi. So I had a bunch of questions here just asking about the risk/reward of taking the interim look on NOTUS. So obviously, that's a foregone conclusion, and congrats on the data, and that's just amazing. But maybe just a commercial question. I know you guys have said sales coverage isn't really an issue here, since you already have the right folks on the ground. But maybe talk about the sales force allocation plan going forward, assuming the regulatory path is what it looks like it should be. And what activities you need to draw from the support COPD, and I know you mentioned that a lot of education is required because docs aren't really used to biologics in this space.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Yes. I don't think we're going to talk directly about how we're going to allocate the sales force. But what we do have is an asthma sales force that's been on the market for several years and knows all the pulmonologists. And there's a lot of prescriber overlap between COPD and asthma. And I believe we're going to be leveraging that sales force to launch the drug. I think we'll have a lot of success there. And I'd add that the results of NOTUS

at a 34% reduction in exacerbations really affirm the high efficacy bar that was set by BOREAS, where we had a 30% reduction in annualized exacerbation rates.

So this is a disease that has no available biologic therapies. Hopefully, DUPIXENT is the first. We plan to file by the end of the year. And with a priority review, could be approved by the middle part of next year and pulling forward that approval by, at least, 6 months where we were previously expecting final results at the middle part of next year. So very excited to be bringing the patients sooner. Yes, there was a little bit of risk involved in the interim analysis but we had confidence that Dupixent would deliver and it sure did.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Okay. All right. Actually, we have more time than I thought. Our clock just started working back from 5 minutes.

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

All good.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Anyway, so here we go. So maybe with that time, let's talk about atopic derm. Obviously, a massive source of growth still with the new patient dynamic, but having invented essentially the market as you guys have, what is natural as you see a flow of competitors. I think you've talked about, even with a growing number of MOAs in the space, exploring a combination strategy with DUPIXENT is not a priority.

Dermatologists, however, do tend to like combination strategies or approaches. Walk us through maybe sort of the remaining growth levers in atopic derm. I know you have expansion into the younger populations, and there is a rising tide, if you will, of new patients coming to therapy. Although interestingly, from our survey work, atopic derm patient load within the physician office is like more than in psoriasis now, how much more growth is there from some of these traditional levers?

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

Yes. I mean that's the beauty about DUPIXENT. 5 indications with a sixth indication coming. And then our largest indication, as Chris was alluding to, is AD. We were talking yesterday with an investor. And we told them that within the AD category, it's not even a teenager yet, meaning that it hasn't even gotten to 13% with regards to penetration, and we think it can go to 25%. So just on the penetration alone and think about it. I mean it's the largest indication on a drug that's annualizing greater than $12 billion off of our latest quarter. And within the largest indication, we're not even kind of halfway there, in terms of what we think we can do with regards to the penetration.

And I think psoriasis, as Chris referenced, is a good reference point to that. Then I mentioned in my opening comments, you know that we have kind of more indications coming for this. But certainly in the earlier age groups, I mean, to think that you can give a biologic to a 6-month old, that's kind of unheard of. You would have never thought that a couple of years back when we were able to get that indication. So there's still more and more and more younger kids, either peds or adolescents that are coming into the kind of this AD category.

And then like with any indication, you start with your most severe, right? So for moderate to severe patients, and we're taking care of the severe, but we do think there's just a whole host of other moderate patients that can kind of come into this category. So Sanofi and Regeneron, we're far from thinking that we're done with regards to AD. We still think there's a ton of additional penetration that can be had in that marketplace.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

All right. One last topic, and it's a big one, obesity. So George has talked rightly about well, GLP-1s are obviously, revolutionary. There are some shortcomings as you start to see more patients coming off therapy, the lack of lean muscle or the loss of lean muscle is likely to be a more front and center, sort of societal issue, I would argue. And I think you guys have been pretty vague about the clinical setup here. You've got a Myostatin blocker, and activin A blocker. Maybe just give us a sense of the news flow and the clinical path, how you might define that?

And maybe a part B to that question. Obesity trials, obesity development is not a trivial spend proposition enough to give a CFO, a lot of heartburn to think about that kind of heavy lift. Is this some area where you think a partner actually might make sense?

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

I'll start, maybe Bob will add on that last bit. But for us, we ran a study in obese nonhuman primates. And I think the next step and we saw a lot of great results, which I'll discuss in a moment. The hope is we will launch a study early next year to hopefully replicate those results next year in obese people. So the nonhuman primate data that we presented at ADA this year combined semaglutide with 2 of our antibodies. One is a myostatin antibody called trevogrumab, and then there's an activin A antibody called garetosmab. So what we saw with these different arms of this study in these obese nonhuman primates was greater fat loss in both the activin and myostatin combination arms combined -- when combined with semaglutide.

And in fact, from the myostatin semaglutide combination, they lost more weight and it was all fat. The lean muscle mass returned to baseline by week 20. The activin A component adds muscle. So the weight loss results were not as impressive over 20 weeks, but we think with the longer duration, potentially higher metabolic rate with muscle, you could end up in the same place as a GLP-1 alone. So we're excited about what we saw in the nonhuman primates. We're going to be launching a clinical study of these different antibodies with an incretin backbone on early next year. And once we understand how this manifests in people, we'll go from there. A partner, I think, could make sense. We're certainly not averse to partnering with leaders in the space. Well, first, I think the goal is to figure out if these antibodies have an application in the obesity category.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Awesome. Okay. Well, we're out of time. So please join me in thanking Regeneron for that.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks. Thank you, everybody.