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Presentation

Akash Tewari
Jefferies LLC, Research Division

All right. Thanks, everyone. Good afternoon. Day 2 of our Jefferies Healthcare Conference. My name is Akash Tewari. I lead our pharma and biotech efforts on the research side for Jefferies. I have the pleasure of hosting the Regeneron management team.

Why don't I hand it off to Chris for some intro remarks and then Ryan for some compliance remarks, which are very important.

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

Yes, we'll start with the compliance remarks. I'll get those out of the way, and let Chris say a couple of opening remarks, and then we'll jump right to your questions.

So I'd like to remind you that 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. Chris?

Christopher R. Fenimore
Executive VP of Finance & CFO

Thanks, Ryan. And Akash, thanks for having us. It's a great conference, and we're very happy to be here.

I think if you look at Regeneron for the third quarter, we came off a very strong commercial execution and performance. You saw $5.1 billion of revenue, basically, which was 36% year-over-year growth. And you saw non-GAAP EPS growth, where it was just over $20 per share, which was just about 70% year-over-year growth. That was largely driven by the commercial performance of our 3 largest growth drivers, each hitting record highs.

So if you look at EYLEA HD, hit just about $700 million for the quarter. Libtayo, which really our commercial team has done a remarkable job in execution on Libtayo, annualizing at about $2.2 billion a year and did about $550 million globally for the quarter. And then obviously, Dupixent. Dupixent continues to do remarkably well, did about $6.5 billion globally for the quarter, about $5 billion in the U.S. alone.

And one thing that we should not forget about in terms of the economics of the alliance is we repaid the development balance, which when we first started repaying it, amounted to about $3 billion. We completely paid that off in the second quarter. So we saw the full benefit of the repayment of that development balance in the third quarter. We'll obviously see that again in the fourth quarter. And then looking forward to 2027, we will also see the benefit of that in terms of comps for the first 2 quarters of 2027.

On the pipeline front, and I'm sure we'll get to some of these questions as we talk to Akash here, is we like to say at Regeneron, sometimes you only see the tip of the iceberg. And we focused a lot of time on our later-stage opportunities in the pipeline. But this time, on our third quarter call, we started to showcase some of our earlier-stage opportunities, which we plan on advancing rapidly, obviously, as rapidly as we can. And I'm sure we'll talk about that.

There's an opportunity in MASH with CIDEB. There's obviously an opportunity with ovarian cancer for our MUC16 bispecific, ubamatamab. And then the last one is an opportunity in POTS, which is postural orthostatic tachycardia syndrome, where we believe there's a significant unmet medical need there. And with our R&D folks in place really working on these programs, our goal is to try and bring these therapies as well as others as fast as we can to meet those unmet medical needs.

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Question and Answer

Akash Tewari
Jefferies LLC, Research Division

Very helpful. So let's start a bit with really what's going on with EYLEA and the franchise. And I can't help but notice, I mean, the strength that we saw in EYLEA, if you look at Vabysmo, they also had a strong quarter. If you look at even some of the GA products, they had a strong quarter. You talk to Roche, they'll tell you, there's been a stabilization on the eye care market, and it's not necessarily as product specific. It seems like it's more market specific. Talk to us about the challenges that we've seen in the wet AMD market over the last couple of years. And would you agree with that characterization that we've actually rebased in the U.S., and we're in a period of more commercial certainty?

Christopher R. Fenimore
Executive VP of Finance & CFO

Yes. So if you look at the market starting in the beginning of 2025, there was what we call affordability challenges out there where patients that are on government-funded programs, in order to get assistance for their copays, need to seek that assistance from not-for-profit foundations. There was a challenge in availability of some of the copay assistance funding, and that really changed the dynamics of the branded market starting in 2025.

What we are seeing now is a stabilization of that dynamic, where I don't want to make light of the fact that the affordability challenges still exist for patients, and that's something that we don't take lightly, and we are prepared to assist those patients, and we have a matching program that's in place, and we're looking for others to basically help those patients that are out there. But from an economic perspective, Akash, you're right, that piece of the market seems to have stabilized in terms of the impact of those patients that were put on an unbranded basically Avastin product.

What we can say is the demographics clearly demonstrate that we would expect the market to continue to grow overall, probably in the low single-digit range, where you've got just an aging of the population and then you've got those unfortunately challenged with facing diabetes and more diagnosis of the diabetic sort of retinal disease category. So that's what we would expect, and we're optimistic about that growth going forward.

Akash Tewari
Jefferies LLC, Research Division

Very helpful. And just to hit on a finer point because -- and I'm personally surprised, it's not like people have stepped up to the plate on the matching program. So it's not like the foundations are, "Now the coffers are filled". No, we're not seeing that. But we have seen Avastin use decline 5% to 10% recently. So there's something else going on. It's not foundations. So talk to us about what's actually occurring, even if foundations aren't getting funded, that's allowing for the affordability issues we've seen with this class to get solved. Is it people getting insurance? Is it Medicare and Medicaid dual coverage? What's going on at the ground level?

Christopher R. Fenimore
Executive VP of Finance & CFO

I think it's hard, Akash, to say specifically what's going on, but you're right, we have seen a little bit of the pressure from Avastin in terms of share backing off a little bit. What we have heard anecdotally, and again, this is purely anecdotal from feedback from the field, is that those patients that are on traditional Medicare Part B, some of them may have been out there securing what they call like Medigap coverage to help with their copay assistance. It's really hard to say how much of that contributed to it. Or there could just be examples of patients that decided based on the clinical benefit, that they were willing to fund some of the copays assuming that they could afford it, but it's hard to say.

Akash Tewari
Jefferies LLC, Research Division

Okay. Understood. Touching a bit on the prefilled syringe. And you talked about, over the last couple of years, there's 3 unlocks we need to have to really get high-dose to reach its potential. You've delivered on 2 of them. Seemingly, cat hair has stood in the way on the prefilled syringe getting approved. But talk to us a bit about your confidence, you still have a pending regulatory decision with the FDA. You've used the term optimistic. So what is your confidence that we could hear back from the agency on your prefilled syringe

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going into 2027? And when we think about how much that unlocks the market opportunity for high dose, what should we be thinking about in terms of, hey, now there's maybe 20% of our patients that have been waiting for a prefilled syringe formulation.

Christopher R. Fenimore
Executive VP of Finance & CFO

So the answer to your question is, we are still optimistic. I mean that's the word that, as you described, we used on our call, and we still continue to believe that we are optimistic in terms of achieving that approval by the end of the year. What I will say is if you look at the performance of EYLEA HD over the course of 2026, what we have seen is, as you've talked about, the unlocking of some of these enhancements to the competitive profile of the product really starting to come through.

If you look at retinal vein occlusion indication, that was somewhere in the neighborhood of basically 20% of the market that we were unable to tap into. And we are now seeing -- now that physicians have the ability to use EYLEA HD, that we're seeing strong performance in that market segment.

The other aspect of their performance is reimbursement confidence. It was really important to the provider community that they had the ability to know that if they prescribed HD, that they were going to get reimbursed for those patients that were difficult to treat. So the fact that we added every 4-week dosing to the label definitely helped in that reimbursement confidence.

As you look at the prefilled syringe and what we think that will mean in terms of going forward towards the end of the year and then obviously into 2027, yes, we believe there'll be some additional inflection. It's hard to say how meaningful that inflection will be. There are some examples, very, very limited where some providers have said they will not adopt EYLEA HD. That's really not that prevalent out there. It's much more those providers that basically have said that they're waiting to see the EYLEA HD prefilled syringe before they adopt it a little bit more broadly in their practices. And we obviously are looking forward to being able to bring that offering to them.

Akash Tewari
Jefferies LLC, Research Division

Understood. And maybe lastly, just on EYLEA, we'll hit on, you have a post-grant review oral hearing on December 4. I will be there, and then a decision sometime in March. But one of the things we published on recently, we find it quite unusual that your counterparty actually offered to drop their post-grant review after going through a substantial part of their, really, the actual review process, and they've gone through depositions as well.

Can you comment, a… and you were given an option, you actually wanted to proceed to a decision. Can you talk a bit about, a, how unusual is it for a counterparty during a post-grant review process to offer to drop a case? Number two, your confidence on that decision and the broader high-dose EYLEA patent portfolio? And then the last part, which I think is quite important, we saw that you had won some of the initial cases on EYLEA, but it really came down to bufferless and non-bufferless. Talk to us about how it might be different this time and whether high-dose bufferless or non-bufferless formulations are really covered with your current patent estate.

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

I'll take that one. A lot in that question, Akash, but I think they're all great questions. To start with the PGR, the post-grant review process is an expedited reexamination of a patent by the USPTO. It's required to be completed within 1 year of institution of a review. So that will come up -- the decision must come by beginning of March 2027. And as you mentioned, oral arguments are to occur in early December, December 4. We feel very strongly that our case that we presented is compelling and that the claims in the '036 patent are not obvious and do not lack written description.

As you mentioned, in our sur-reply that was filed a couple of weeks ago, we did mention that Alvotech approached us about mutually withdrawing the post-grant review that they petitioned for, and we declined that offer. We agree with your assessment that it is a bit unusual, especially at this stage in the process, for a counterparty to approach the patent owner and ask to withdraw. Unclear on exactly how common that is or not, because most of the time, these things never come to light, never get publicized if they occur at all. So I don't know how to comment on whether or not it's unusual overall, but to us, it struck us as unusual.

In terms of the strength of the patent estate, we, again, view the '036 patent to have valid claims, but we also have additional IP that can support EYLEA HD's marketing exclusivity in either the late 2030s or even in the 2040s. And these are patents that are either issued or are pending that will cover methods of treatment as well as the formulation and manufacture for EYLEA HD. So we feel

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very strongly that while the '036 patent is important, there are other patents that can continue to support its exclusivity well beyond the 2020s and into the late 2030s.

Lastly, I think we can't provide any certainty on when these biosimilars will launch, but the bufferless issue is something that we feel pretty confident in, because our '036 patent is silent on whether or not a buffer is required or not. And part of the issue with the 2-milligram formulation patent was that it, in fact, was discretely listed as a component of the formulation. That is not the case for the '036 patent. Because it's silent, we don't view required to have a buffer or to not have a buffer as being relevant. So we would feel comfortable with either infringing our patents as long as they are infringing other claims.

Akash Tewari
Jefferies LLC, Research Division

Understood. Now going into next year, and it was interesting, I was talking to a long-only, and he goes, "Akash, part of the reason why Regeneron had such a strong couple of quarters is, when I look at the number of positive estimate revisions, Regeneron is #1 of all large cap therapeutics, #2 is actually Lilly". I mean it does tell you about, again, removing the kind of uncertainty on numbers has had a big overhang relief in terms of the share price.

I look at next year, and I know, obviously, you're not going to comment on guidance, but there does seem to be a tremendous amount of operating leverage. If you have stability in EYLEA, you have a rebasing on the Sanofi agreement and then you have the continued performance in Dupixent. I mean people can get $75, $80. I'm not going to say: bless that number. But talk to me about how much operating leverage the team has going into '27 and beyond. And do you feel like now that the Sanofi agreement has been rebased, you're really in a new -- when it comes to earnings and earnings growth, you're in a different trajectory than you were in the last few years?

Christopher R. Fenimore
Executive VP of Finance & CFO

So thank you, Akash. And yes, you're right, we won't necessarily provide any guidance, but more than happy to provide some commentary in terms of directionally how we see things.

I think you're right. And the way we kicked off the conversation today is we've got 3 sort of primary growth drivers as we look at the business at least today, and then obviously more to come in the future. We expect those growth drivers to continue to drive, obviously, some top line growth.

With that being said, as we think about our capital allocation sort of philosophy, our #1 priority is investing in our own internal R&D capabilities. We did say on the third quarter call that we expect our investment in R&D to increase year-over-year at a mid-teens percentage. So that's obviously something, at least in the short term that would impact some of that operating leverage, but we clearly believe that, that's the best thing to do in terms of generating long-term value for our shareholders and obviously, to bring new products to patients in need.

The other thing that I would point to as we look at SG&A, and again, we're not necessarily providing guidance, but there is obviously an inflationary environment out there, and we're doing all that we can to manage what's happening out there in the broader sort of macroeconomic environment. And I'm sure we'll touch upon it briefly. We're going to launch our product in myasthenia gravis, cemdisiran. And that launch is a new area for us. It's a specialty launch in neurology, and that will require some investment in terms of SG&A.

Akash Tewari
Jefferies LLC, Research Division

Understood. Now it's interesting, the last couple of years have been choppy. Your stock is at an all-time high. The EYLEA biosimilar entry happened and there was this kind of period of uncertainty. And I think it's interesting, Len and George, I don't know if they'll ever admit it, but there is a sense with them that they listen to shareholders, they listen to internal stakeholders within the company, including, I assume, also both of you. And it is kind of notable, like when you think about the tone on the Sanofi partnership, the tone on BD, this doesn't seem like the Regeneron stance that it's had historically. Your team has gone out to say, no, this is different.

For investors who are skeptical that, a, there is a market change in terms of M&A priority, the types of acquisitions, the risk profile and also the deal size, what would you say? Do you feel like there is a renewed focus and a different strategy than what's been out there historically for your team?

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Christopher R. Fenimore
Executive VP of Finance & CFO

Yes. Again, this came up on the third quarter call. I don't think there's necessarily a change in philosophy in terms of the way we view external opportunities. As I said earlier, clearly, the first priority for us is investing in our own internal capabilities. But we have a tremendous amount of flexibility with the balance sheet that we have to look at opportunities.

We judge those external opportunities the same way we look at our internal pipeline is what does the opportunity bring to us? What is the risk reward profile of a given opportunity? What do we think the trade-offs are in terms of, obviously, probability of success relative to the investment required. And ultimately, how does that product look like it will fit out in the marketplace? And is it first to market? If it's not first to market, how is it differentiated? And those are all the criteria that we assess when looking at external opportunities.

But I think the other thing is, we're extremely disciplined on valuation. As we evaluate opportunities, we're not afraid to necessarily put capital to work, and we will if we find the right things that we think make sense, but we're going to do it in a very disciplined valuation-sensitive approach where some of our peers or competitors out there may have a different lens in terms of what they perceive the appropriate value to be for a given opportunity.

Akash Tewari
Jefferies LLC, Research Division

Maybe -- we'll be hosting Gilead here shortly thereafter. And you'll talk to Andy about how he thinks about BD, he'll -- the word discipline comes a lot. But a lot of that is also -- it seems like BD strategy is also underwritten by where you are. Am I a patent cliff company? Am I a company that has a long runway? I feel like with Regeneron, it's interesting, your team has said, we feel confident that Dupixent IP will go out broader than what maybe the Street estimates. And by the way, I would personally agree.

But at the same time, I do think there's a desire on the investor side of, look, just give us some revenue diversification, pay a fair price, but it's more an appetite for derisked assets that are commercial stage and can really diversify the company away from Dupixent. So where do you feel like Regeneron is at in terms of "I'm Lilly, I don't -- or Gilead right, I don't have a patent cliff and I can take risk" versus "I am willing to pay fair value for a commercial stage asset because I really want to diversify this business and give investors -- present this as a multi-asset story."

Christopher R. Fenimore
Executive VP of Finance & CFO

So I think, Akash, we clearly listen to the investment community, and we appreciate there is a desire by some that we would do more external M&A. And I just want to reiterate, we're not opposed to doing external M&A. It's quite the opposite, honestly. We've got a fairly robust effort out there. Our business development team is constantly looking at opportunities. And if the right opportunity presented itself, or multiple opportunities, we definitely have the flexibility to do that.

I do think as we look at the business, and while we recognize, obviously, as the decade turns and you alluded to sort of Dupixent and the franchise there, we really feel that the internal pipeline that we have can deliver on that revenue diversification and really drive the next wave of growth for Regeneron as we think about the turn of the decade.

Akash Tewari
Jefferies LLC, Research Division

Understood. And maybe just last question on BD. And it goes back to kind of the Sanofi partnership. And it's interesting when I've talked to your team, one of the things that you stressed is, look, that initial announcement is a part of a really wholesale renewed partnership between both companies. And the 4 assets that you've put in, it doesn't mean that this is "in". And even if you look at the deal documents, you have the ability to in-license an additional early-stage asset from Sanofi.

What becomes kind of interesting there is, look, if we're thinking about I&I assets out there and we're thinking about, hey, what can plug and play into this renewed partnership between both companies, I almost think the acquisition shouldn't be a Sanofi or Regeneron. It could be a joint acquisition instead of one company acquiring an asset. Does that framework make sense to you when you think about looking at it externally to in-license assets into this I&I partnership you've announced with Sanofi?

Christopher R. Fenimore
Executive VP of Finance & CFO

So I mean the first thing I would say, Akash, we're obviously quite pleased to have announced that expansion with our colleagues at Sanofi. I think Belen has done a great job of really changing the tone of the relationship. I think you've heard them talk about trust and

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transparency. And the relationship is really off to a fantastic initial start after this expansion, and we're looking forward to really doing great things together, obviously, with the 4 assets that are at least initially in the expanded alliance.

I will say there's nothing about the new and expanded agreement that would prevent either party from bringing things internally from their own R&D portfolio into the alliance. There's no obligation, but there's nothing that would prevent us from doing that. We'd obviously have to negotiate what that would look like. And there's nothing that would prevent the alliance of finding an opportunity jointly that would make sense to do it together rather than compete against one another.

And I think we'll know what makes the most sense when those opportunities present themselves. And that will be really the decision-making sort of analysis of are we better off doing this together or are we better off doing it alone? And we won't know that until we actually see various opportunities that come along.

Akash Tewari
Jefferies LLC, Research Division

Understood. Maybe lastly, on CIDEB, and it really is an impressive profile. I mean, 6 months potential dosing, 70%, 80% liver fat reduction. I mean that is a profile that I think a lot of people would have wanted for the class along with the tolerability.

Talk to me about how the development path of CIDEB might be different from what we've seen historically within MASH. And how much of that difference could be driven by, a, we have a genetic target; b, we're going for MASLD as well as MASH; and c, we have such a clean safety profile. Do you think the product profile itself also fits into the regulatory path to the market with the agency?

Ryan Crowe
Senior Vice President of Investor Relations & Strategic Analysis

I think my best answer at this point is maybe, and we certainly want to have alignment with the FDA as we embark upon the registration-enabling studies. What we have planned is a Phase IIb study that will be 1 year in duration. It will have a primary endpoint of liver fat reduction at week 26 as well as biopsy data at week 52 regarding fibrosis as well as MASH resolution, which is a common path that other MASH therapies have gone down. To the extent a noninvasive endpoint could be incorporated in the design, we certainly will have that discussion with FDA. But right now, we're comfortable with the design that we're going to present to them and have that conversation and go from there.

Akash Tewari
Jefferies LLC, Research Division
Understood. We're out of time, but I really did appreciate the discussion. Thanks so much, everyone.

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