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EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at Jefferies Global Healthcare Conference

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OVERVIEW:

Company Summary

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CONFERENCE CALL PARTICIPANTS

Akash Tewari Jefferies LLC - Analyst

PRESENTATION

Akash Tewari - Jefferies LLC - Analyst

Thanks so much, everyone. It's funny, I was talking to an investor and it was his first time in London, and he goes, it's not that crowded and I think it's going to be okay. I told him, just you wait. It's not going to be a problem, but it's so great to see everyone. My name is Akash Tewari. I'm a pharma and biotech analyst here at Jefferies. We have the pleasure of hosting the Regeneron team.

Why don't I hand it off to Ryan to give some compliance-related remarks, and then we'll get started with Q&A.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Thank you, Akash, and I agree. It's a very well-attended conference, and thank you once again for having us. We're always excited to be here and share the Regeneron story. Before we get started, let me read this forward-looking statement disclosure.

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.

Akash, back to you.

QUESTIONS AND ANSWERS

Akash Tewari - Jefferies LLC - Analyst

Perfect. I feel like I was listening to a Dupixent commercial. So thanks so much. And again, we're very grateful to have you. Chris, I'm going to start off this question. This is the number one question we're getting kind of on EYLEA, where it's been funny talking to Regeneron, been talking to Roche, and there's differences in terms of when foundation funding has an impact. When does pricing have an impact.

And I think the number one question we're getting after Q3 is like if we look at Vabysmo, we saw real pressures in terms of volume growth. And when we look at high-dose EYLEA, you guys really stood out, right? You were growing double digits from a volume perspective. And it does seem like your team has really retooled. That would actually be the way I describe it, your commercial strategy, and it's having an impact on the bottom line.

Can you talk to us, to the extent Len will let you, what is going on at a ground level on EYLEA that's allowed that franchise actually return to growth from a volume perspective for high dose?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

Thanks, Akash. And again, thanks for having us here. It's really, really a pleasure. So as you pointed out, Akash, we've seen EYLEA HD over the course of the first few quarters accelerate in terms of sequential unit growth demand. So we saw 5% growth in the first quarter, 16% in the second quarter, and then 18% demand growth in the third quarter.

In terms of your question of what have we been doing, I think we've been doing the same thing all along, which is our commercial organization. The field team is out there. They're talking to physicians. They're getting physicians the word out in terms of the differentiation of the product. And they're now starting to see based on real-world experience with patients, how their patients are performing, both in terms of efficacy and durability, and that's starting to resonate with the community.

In terms of what we've said for the fourth quarter, we expect the growth to moderate a little bit. And we said we expect that to be high single digits. And we also noted that there's -- obviously due to the competitive nature of the market, there's been continued pricing pressure in the market.

And in terms of future demand, we get a lot of questions on what we expect future demand to be like. We truly believe that the enhancements that we've talked about are important to continue with that growth and to see an inflection in that growth in terms of the demand for the product, and they're very important.

So as we talk about them, we've got every 4-week dosing, which means a lot to the physician community as they want to ensure that they've got reimbursement confidence. They don't want to be in a situation where there's a certain small subset of their patients that don't get out to 7 weeks. And they want to know with confidence that if they prescribe EYLEA HD that they are going to get reimbursed and not have the risk of, obviously, financially as well as the complexity of having to switch their patients to another competing therapy or an unbranded type of therapy.

Obviously, RVO, another opportunity that is very important, upwards of high teens to close to 20% of the market in terms of the way we look at it. It's something that today we can't touch, and we look for the opportunity to obviously add that to the label as well. As you think about it in terms of physicians, when they're stocking their fridges, they want a product that is one-stop shopping. So there's a certain segment of the market that may be holding back a little bit at least in terms of their willingness to prescribe EYLEA HD.

And then the last thing is obviously the prefilled syringe, also a very important thing for the physician community in terms of flexibility and ease of administration. And if you look at the EYLEA 2 mg franchise, I think it's upward of 95% of physician preference is to use a prefilled syringe. So obviously, also a very important component of driving that future demand for EYLEA HD.

Akash Tewari - Jefferies LLC - Analyst

Understood. I don't know I'm going to let you get away with it, it's all been the same. No, because I think one of the things that I noticed, and I feel like I was surprised, I think your team may have also been surprised was Amgen was employing -- you've seen Novartis with Cimerli give volume-based discounts. I don't think you've seen a company give long-dated reimbursement, where you're basically accruing like an accounts receivable for two years. And I think Amgen's strategy really would resonate if you're a very high-volume practice, right?

Talk to me, maybe to the extent you can, about what your team has done to kind of neutralize some of that strategy. And again, on the pricing impact, right, you saw kind of an 8% price impact in Q3. I think the big question for a lot of investors is, should we kind of assume that that continues on a go-forward basis, or would it revert more towards kind of a 1% to 3% ASP decline that we've kind of seen historically with the class?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

So I think for competitive reasons, Akash, we can't really comment on our pricing strategy nor of the strategy of our competitors. All I can say is our team is very well aware of what is happening out there in the marketplace, and we respond accordingly in a way that we feel is necessary to ensure that while the messaging is getting out there on, obviously, the benefits of the product that we're also competing in what is a very competitive marketplace.

Akash Tewari - Jefferies LLC - Analyst

Understood. Now maybe just on kind of foundation funding. And I will say -- and I wouldn't just say this unless I meant it. You guys were literally funding everyone's -- like I think you had a right to feel like we're spending the vast majority on Good Days. We're the ones helping patients, and there needs to be more kind of equitable distribution. I think there's no doubt.

As you go into next year, I think the concern for some investors is, well, there's about a 10% impact in terms of patients who couldn't get on supplemental insurance. And I expect another kind of 10% impact as we go into next year. Your team has talked about a matching program. I feel like demand from your peers has been disappointing so far.

So I guess the hard question becomes, if there is no shift in kind of the status quo, will Regeneron commit to funding the patient assistance organizations to the same level they did historically, or there's no way this restarts unless there is, again, more equitable share?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

So I think, Akash, you hit the nail on the head in terms of our belief and philosophy is that patients should be able to afford their medicines, and we want clinicians to obviously prescribe the therapy that their clinicians believe is the right one for them. The unfortunate thing is, as you stated, there is affordability challenges out there. We felt, as you've highlighted, that it's nearly impossible for us to support all of demand that's out there. That is why we instituted a matching program in the middle of this year with the goal of matching dollar for dollar, any contributions that were made to a particular foundation up to $200 million by the end of the year.

We announced with our earnings call that the contributions thus far were unfortunately disappointing. It was less than $1 million that we had to match in the third quarter. We continue to be optimistic that others will participate and take advantage of that matching program because we think that's a great thing for patients.

In terms of what we will do for 2026, I continue to say that we want to do the right thing by patients. I think it's too premature to say exactly what our strategy will be other than that we want to see contributions happen under this matching program because we think that's the best way to get affordability sort of issues resolved for patients.

Akash Tewari - Jefferies LLC - Analyst

Understood. And maybe just a bit of a nuance here. It does seem like maybe Roche is putting out some funding. It's not a huge check, I know, but it seems like it might not be through Good Days. So this is a question I think we get from investors.

Let's say you do hear a funding returning, not through good days, but towards patient assistance for wet AMD patients, would that be recognized as a match under your current program? And would that maybe change, and you would recognize that as a matching donation, right?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

So in terms of our contractual obligation with the charity, it is for contributions to their fund. If we were to hear of other contributions being made to other funds, we'd have to evaluate if and when that would happen. As of right now, we have not heard of that.

Akash Tewari - Jefferies LLC - Analyst

Okay. Understood. Now you talked about the label enhancements, and I agree with you. I think they could be super important. But I also want to make sure investors are kind of level setting, right? And especially your stock was up to date, you had an OAI, certainly from, I think, the long only -- it doesn't matter if it's at the end of the year, it doesn't matter if it's midyear, it's more when it comes.

If I was thinking about reasonable expectations, Scholar Rock, I think, mentioned that there is going to be -- they're at least available to have an FDA site inspection at that Bloomington facility. What is Regeneron's kind of internal confidence on at least two of the labeling enhancements happening by year-end with a potential December inspection versus you know what, just be conservative, really expect something more midyear and Q1.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Yeah. Thanks for the question. I think we're focused on getting these label enhancements into the EYLEA HD label as quickly as we can. Certainly, the setbacks with Catalent have been disappointing, and we're working as quickly as we can with alternate fillers to get a compliant one onto the BLA so we can get these enhancements approved. Just to refresh everyone, there's a PDUFA date later this month for RVO and Q4 dosing.

If there is no compliant filler on the BLA, and really the only one that it could be at this point is Catalent, we would expect to get a CRL. So I think that should be your base case for the November PDUFA date. Importantly, in late December, we have a PDUFA date with this alternative vial filler. Should they be able to pass inspection and get added to the BLA at that time, we would then immediately resubmit that sBLA for Q4 dosing and RVO and would hope and expect the FDA to act relatively promptly, given the only issues related to that file are related to a compliant filler. So there's a potential outcome where we can get Q4 dosing and RVO on the label before the end of this year.

I think on the prefilled syringe, which is on a different track, and we're using a different alternate filler, the timeline we've defined is that we're currently in validation runs and completing that work shortly, and we intend to file with the FDA with this alternate prefilled syringe filler by January, which would trigger a four-month review. So I would say sometime in the second quarter is probably a good base case for when prefilled syringe could come to the market. So yeah, we hope that both of these can be accomplished certainly in the first half of '26. And then we would expect the brand to accelerate even faster than it has in these recent quarters.

Akash Tewari - Jefferies LLC - Analyst

Understood. Now Ryan, you and I have talked about this. You think about the inflection, you're already seeing an inflection on volume on high-dose EYLEA, but it gets a little provocative. I mean, 10% of your patients are impacted by these foundations. Let's hope that gets resolved next year.

20% of your patients on EYLEA are RVO. About 1/3 of patients on EYLEA are monthly dosing. And paradoxically, those would be the patients, I would think would be the first to try high dose and because you don't have the monthly dosing, they're the ones who are maybe trying another treatment. I mean, that's 50% of your patients that theoretically high dose would suddenly be able to unlock. When we think about the magnitude of inflection that could occur if you can get these label, like help us understand what the trajectory could look like as we get into the back half of the year and then '27.

And then maybe stepping back, would potentially the EYLEA franchise in the US return to growth going forward, or are we talking more about stabilizing growth where the high-dose growth offsets the low dose growth?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Those are all great points, and I think we agree with most of them. Certainly, these enhancements, we think, are the key to unlocking the full commercial opportunity for EYLEA HD. We're not willing to kind of quantify what we think this brand is capable of. But in the segments of the market where EYLEA HD currently competes, which would be in RVO -- I'm sorry, in wet AMD and DME and in patients that are dosed at least every seven weeks, we are -- we have the plurality of share. So we are winning where we can compete.

And I think once we have these label enhancements in place, we will win there as well. With RVO, we expect to be the only product that's approved for every 8-week dosing, and we don't expect to have a durability cap on it as Vabysmo does at 24 weeks. So there's some competitiveness there. And certainly, we believe our prefilled syringe device is going to be best-in-class. So we're looking forward to bringing these to doctors and to patients.

But I don't think we're ready to kind of go out on a limb and project exactly what that ultimate commercial opportunity looks like.

Akash Tewari - Jefferies LLC - Analyst

Understood. Chris, I know you get -- there's always the question of when will Regeneron guide, and you guys have never really historically guided. But I look -- I mean, the way we kind of think about this, if I talk to a Sanofi investor, they'll often say Dupixent's NPV is around $40 billion, you are approaching $20 billion in cash. I mean, you're getting to a place where I think you could be a deep value type play. From a Board perspective, from a C-suite perspective, right, you've been historically a growth company, you're being treated as a value company.

What can you do from kind of a CapEx perspective, a communication perspective to kind of get out of that bubble and like maybe add more certainty on how the business is going to perform until the end of the decade?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

So there's a lot packed in that question as well, Akash. We obviously have a number of avenues. We firmly believe that investing in our internal capabilities is the best way to return long-term value to shareholders. We will continue to do that. We get asked a lot of questions about business development and M&A and our appetite for doing M&A or even larger scale deals.

And our response to that is always, we have the tremendous flexibility with the balance sheet that we have to do deals that make sense. Our team is actively out there, regularly evaluating opportunities. And we've looked at things that are either complementary to things that we have from a technology perspective or even complementary to what we have in terms of commercial types of franchises. And Len has been quoted as basically saying, he doesn't want to spend $8 billion, $9 billion, or $10 billion and turn that into $2 billion. We have to find the right opportunity, and we just haven't found that yet. But we, as I said, have the tremendous amount of flexibility to do that.

In terms of capital, besides business development, we have a very active capital program. Just hit the news, at least New York State put out a press release last week that we are investing in another facility in New York State, about $2 billion to expand our manufacturing capabilities to support the pipeline, and what we believe the future will deliver from that pipeline. And then we're also putting capital to work in terms of expanding our R&D facilities in Tarrytown.

So we're very mindful of the cash balance. And we've got a very active share repurchase program as well as a dividend program that we initiated earlier this year. So a lot of ways to put capital to work.

Akash Tewari - Jefferies LLC - Analyst

I want to hit on something that I think came up at our brunch, and I think it's important. I mean, if you continue to generate cash, your team continues to generate cash at its current rate, you could end this decade with free cash flow in the kind of $30 billion to $35 billion range. I mean, that's -- you'd be one of the only large-cap biotechs, where cash is a bigger percentage of your EV. I don't know if you want that much cash on your balance sheet, right? Like what's the right amount of cash that you'd want on your balance sheet?

And then doesn't that kind of imply that there is going to be larger M&A from the Regeneron team, right? I can't conflate the two, either your share buybacks meaningfully increase from even here, your dividend meaningfully increases, or there is going to be some large-scale BDM in the works.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

I think it's hard to comment on what the ideal amount of cash is to have on the balance sheet. I would just say to you, Akash, we feel that we've got opportune areas to deploy that cash, and we will work on ways to put that to work to generate what we think is the best way to return shareholder

value. I don't foresee a scenario where we'll accumulate $35 billion in cash, and we will work hard to make sure we deploy the capital in the best interest of our shareholders.

Akash Tewari - Jefferies LLC - Analyst

Understood. Maybe just hitting on your pipeline, and this is kind of an observation I've noticed, and I wanted to see how crazy I sound. You just had the Trump Rx deal. And I think one of the things that's missing is that's a deal that seems to be not just available to Lilly and Novo, but any treatment that's making -- getting into obesity in the future. You had in-licensed the Hansoh GIP/GLP, and I think a lot of investors are like, oh, I was looking for something more aggressive. You guys have always talked about your GIP/GLP more as like an add-on asset where you would add on other MOAs.

But what about just the asset itself, right? You -- that Hansoh Phase 3 in China reads out in Feb. You very well may have a 20% to 25% weight loss product with almost an identical profile to tirzepatide, and you could be launching within, let's say, six months to a year of MariTide. I look at MariTide estimates and then I look at your pipeline for sell-side. I mean, no one is giving you credit for just the weekly GIP/GLP.

Are we making a mistake here? What is the market opportunity on just that asset alone?

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

So I mean, Akash, I think you definitely pointed out that our purpose of in-licensing the Hansoh asset was to have it be the backbone of a lot of combinations that George and his R&D team think would make sense going forward. But as part of that, we need to develop the program as a monotherapy. So there is the potential upside that we could recognize some incremental value from the monotherapy sort of deployment of that particular asset. With that being said, our intent is not to compete with some of the larger players that are out there. It's a very dynamic environment.

There was another pricing announcement made by one of the players this morning. We're obviously watching it very closely. But I think that the future of that asset is in the hands of our senior leadership team is we will find the best way to sort of monetize that to find the right value, and it could be a combination of combinations as well as figuring out what might be addressable on the monotherapy side as well.

Akash Tewari - Jefferies LLC - Analyst

Understood. And maybe just on a finer point on that. The sense I've gotten is your interest on myostatin has -- I mean, you still talk about it, but it's not the first thing you talked about when it comes to obesity. And then I almost think there's a play with I&I with some of these -- I mean, you think about HS, these are areas that Lilly is looking at, you think about vascular dementia, right? You can look at a GIP/GLP not just as a pure-play obesity asset.

How is Regeneron thinking about that GIP/GLP in indications that maybe we're not thinking about that might also combine with your life after Dupixent, and it sounds like we'll hear more about that going into next year.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Yeah. No, I think we still have optimism about myostatin, and we still have a lot to learn about it as well. There's some provocative data in subsets of patients that we haven't disclosed yet. We're also waiting for the maintenance data. That's when all patients in this COURAGE study drop semaglutide and half remain on high-dose myostatin.

Are they able to maintain the weight that they lost during the 26-week weight loss induction phase. So we'll see what that looks like in the first half of '26. Beyond that, there's a Part C to this COURAGE study that's going to look at myostatin over a longer period of time over a full year as

opposed to only 26 weeks, where the weight loss curve is really still in decline as opposed to plateauing. So we still have some things to learn about myostatin and its effect on lean mass preservation and weight loss.

But to your point, there are other opportunities in comorbidities of obesity that we think we have either the portfolio or the pipeline opportunities to address. And part of our differentiation strategy is bringing those in combination with this Hansoh opportunity as well as some other incretin-based technologies we have in our preclinical pipeline that perhaps can address some of the other unmet needs in the space.

Akash Tewari - Jefferies LLC - Analyst

And I can't help but notice you're not calling out the leptin. You do have that study in collaboration with Lilly. I think that's always kind of an interesting, quote-unquote, healthier weight loss play. Where does leptin add-on kind of fit into your portfolio? Is this something we should be digging into or probably not?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Yeah. So Lilly has been conducting the study, and I'm not exactly sure on the timing for when it reads out. I would guess sometime next year, but I don't have a more precise timeframe for that. The hypothesis is that with dramatic weight loss, patients can become leptin-deficient and by agonizing leptin, you can actually break through the plateau. We'll see if that plays out.

It's very much an experiment, I'd say. So dependent on the results, it could become a really big part of our strategy or much, much smaller part of our strategy in obesity.

Akash Tewari - Jefferies LLC - Analyst

Got it. Factor XI, and we just saw the Librexia ACS study fail, I think, Friday, I'm losing track of time. I think one of the things -- I feel like people look at it very binary. It's like the mAbs, the orals and then there's a target. And I don't know if people really appreciate you have two different mAbs, but then also your development program is not going for maybe the same indications.

So can you comment on, A, when you think about ACS, but also stroke, right, Asundexian has a big stroke study coming up. Do you feel confident that, that's maybe the right place for Factor XI? And number two is, if not there, where do you think Factor XI will really have clinical benefit?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Investor Relations & Strategic Analysis

Yes. It's unfortunate news for the milvexian program and their failure interim in acute coronary syndrome. We do not have Phase 3 development plans in that indication or in secondary stroke prevention, which is the next anticipated readout in the class for Asundexian from Bayer. We view those as less genetically supported. And rather, we think that venous clotting is you're likely to have more activity with venous clots such as in a post knee replacement setting or in cancer-associated VTE.

And then we also are looking at it. The overlapping indication we have with the orals is in stroke prevention in patients with atrial fibrillation. So our differentiation, I think, comes from having these two different antibodies, which we think will have distinct therapeutic profiles because they block different domains on Factor XI. Our A2 antibody blocks basically the domain that activate -- that Factor XII activates and then starts to cascade. We've seen in the early settings as well as in preclinical assays that there's less anticoagulant activity, but we believe that Factor XII knockouts based on genetics data have no increased risk of bleeding.

The other antibody that we're developing targets the catalytic domain as do the other antibodies and small molecules in the class. Here, we see dramatic APTT time to clot activity with this antibody relative to others in the field and complete blockade of thrombin, which we think is essential for it to have dramatic anticoagulant effects. So we think that there might be more bleeding risk with that more potent anticoagulant, but still an

acceptable level of bleeding such that it can be at parity at minimum with the Factor Xa's, but not increase bleeding risk as Factor Xa's do. So we are looking to tailor our approach and allow physicians and patients to decide what the appropriate treatment for them is based on their anticoagulant needs as well as their tolerance for bleeding risk.

Akash Tewari - Jefferies LLC - Analyst

Understood. I know we're out of time. Guys, thanks so much for joining. Again, thank you.
