REFINITIV STREETEVENTS

EDITED TRANSCRIPT

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

EVENT DATE/ TIME: NOVEMBER 15, 2023 / 2:30PM GMT

OVERVIEW:

Company Summary

REFINITIV

CORPORATE PARTICIPANTS

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

Ryan Crowe Regeneron Pharmaceuticals, Inc. - VP of IR

CONFERENCE CALL PARTICIPANTS

Akash Tewari Jefferies LLC, Research Division - Equity Analyst

PRESENTATION

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Good afternoon, everyone. I was just joking with the Regeneron team that there's a biotech bear market. I don't see it in London. These are packed rooms. It's really great to see everyone. And this is -- I also think that we're going to have an XBI rally. But that's my hot take for the day. That aside, I do have the pleasure of hosting the Regeneron team, Bob Landry, CFO; and then Ryan Crowe, Head of Investor Relations.

I will hand it off to them to make some introductory remarks and then we'll get started.

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

Thanks, Akash. Great to be here again. And this is a very crowded conference. I think it might be time for a bigger hotel.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

The claustrophobia is a feature, not a bug...

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

I see. Anyway, I'll do some FLS disclaimer and then Bob will have a couple -- a minute or 2 on opening remarks and then we'll get to Akash's questions here.

I would like to remind you that remarks made today may include forward-looking statements of our 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 Bob, take it away.

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

Yes, thanks, Ryan. And Akash, thanks for the invite. I think Regeneron has been a regular for the last couple of years at this conference. And it draws an incredible investor base. So we're very happy to come here.

So we're fortunate. We just had our third quarter earnings kind of less than 2 weeks. So I was going to spend maybe 2 minutes on kind of refreshing everybody, giving them a quick deep dive into what we talked about. And then I'm assuming, Akash, we'll go deep on a couple of these things.

So we were proud on the third quarter, we had top line growth of 15% on revenue. We were 4% on the bottom line. We did take $100 million IP R&D charge relating to the milestone that we paid for -- to Alnylam for the ALN-APP drug. So we're more than happy to pay that. If you consider that not there, we actually grew 11% on the bottom line.

EYLEA HD, which I'm sure we'll get into, we had a strong quarter. We were very happy with the quarter. It was true demand. It was $43 million. It was above consensus, certainly above what VABYSMO, our competitor, did. We were on the market for 6 weeks. I think it was the third week of August that we launched. So it was proud.

In the third quarter, we talked also about our 2-year data with regards to PULSAR, which again is the EYLEA HD. And I think people are realizing that it is going to be the new kind of standard of care with regards to the 8 mg within the VEGF category. So we're fine with that.

And we came away with market share. We normally give category market share at 45%. So if people want to know what the EYLEA franchise is within the anti-VEGF category, including Avastin, it's 45%, which was, I think, almost like a 50 basis point slip versus Q2. So we're holding well there.

DUPIXENT, again we'll get into that, did $3.1 billion for the quarter, up 33%. Again, this is a product, I think, that launched in 2017. And to grow 33% on the baseline that we have is really kind of fantastic. Our margins continue to improve on that.

For those that follow the Regeneron story, we talked a lot about our cell bank that we use to make drug substance in which we're getting kind of a 3x benefit, and people are seeing that. I think year-over-year, our margins on the DUPIXENT brand are up like 400 basis points. Ryan was reminding me, we pick up like 100 basis point improvement every quarter. And there's still a lot of life left with regards to that.

We made big news on COPD. So going into the third quarter, the question was we are in discussions with our Sanofi colleagues on whether or not we can do an interim look. We knew that at the time of our announcement, it was a material event. So we did tell our shareholders that we have been in contact with the FDA.

And they have agreed that for the NOTUS trial, which is the second of our COPD trials, we read out the BOREAS trial in the first quarter of 2023, that with the NOTUS trial that we'll do an interim look in the fourth quarter. If it's positive, we're going to be able to bring COPD in Sanofi, Regeneron and Sanofi will be able to bring COPD to market 6 to 9 months earlier.

And just to kind of size the prize on that, there's about 500,000 people of kind of Th2 disease for COPD in the G7. So it is a big, big category. And we'd love nothing more to certainly bring this to help these patients out sooner rather than later. And I think it's the third leading disease in the world. So it is certainly a health crisis there.

LIBTAYO, our PD-1, continues to do well. We're actually annualizing at $1 billion on that drug. We continue to make headway. CSCC is our main indication, but we are making inroads on non-small cell lung. That's all fine.

Pipeline stuff. We do have odronextamab, which is our lymphoma drug. It has a March 31, 2024, PDUFA date. This is really our first entree into heme onc. We have a couple of heme oncs coming into the market. Odro will be the first one. We know it's a crowded market. We will not be first. But we think it's a good drug, and we're going in later lines. And the goal is obviously to go into earlier lines, where we anticipate we're going to be that much more competitive.

We also have a filing for our BCMAxCD3. We're going to do that in the fourth quarter. The data on that looks very, very strong. Again, with DUPIXENT, we have another kind of indication, this is pediatric EoE. EoE has proven to be a bigger category and a better category than we actually thought it was when we launched it. We have a PDUFA date on January 31, 2024.

And we actually closed our second acquisition, albeit very small, with regards to Decibel in September. It was basically cell gene auditory therapy. And we actually had our first patient, right before our earnings, basically get injected with this cell gene therapy. And although it's a rare disease, this DB-OTO, we had -- again, early days, we had success with that. And we're actually going to obviously continue to dose patients on that.

So pretty exciting quarter, whether it be the numbers or the pipeline or everything going on. And certainly, COPD was a nice event. So Akash, with that, I'll hand it over to you.

QUESTIONS AND ANSWERS

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Awesome. Thanks so much. So I want to start off with maybe a question on BD. And like if you kind of -- I always joke with clients, I think there's been almost kind of a spec pharma-fication of M&A. And you can see this on the IPO side. You can see this in terms of what pharma actually acquires, right? And to a certain extent, you follow the winners, right? Like you look at what Lilly has done. They didn't diversify into five different things. They honed in on obesity and Alzheimer's and then they took a long time to kind of develop these products, then they had follow-ups.

When you think about your BD strategy, right, why not -- especially given you're going to have $10 billion in terms of cash on hand and you have really good visibility in terms of runway, why not start looking at more commercial-stage assets, start paying off $5 billion, $10-plus billion in order to add something on to your DUPIXENT franchise, add something on to your EYLEA franchise that's synergistic? That hasn't really been your approach to BD over the last couple of years. It seems like it's more early stage. But what is your appetite to potentially move up and start looking at some of these later-stage deals?

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

Yes. A lot of people think that it's just -- it's outside our DNA. I mean, I wouldn't say that I would say something transformative would be outside our DNA. Kind of buying a late-stage Phase III kind of revenue filler would be outside our DNA because I think our management team thinks that there are a lot more desperate people out there that are willing to pay what the value -- so much more than what we would be willing to pay on that. So we've kind of had that as no-fly zone.

But we remain super interested in kind of technology plays. We love platforms. We love franchises. We like things that can kind of combine with antibodies. We have an RGC, a Regeneron Genetics Center, where we've sequenced over 2 million exomes, I think, almost half of what's been done in the world. So we have a treasure trove of what kind of what the targets are. All the targets are not always fit for antibodies.

So we do need other technologies, whether -- I think we've shown that with Intellia with regards to CRISPR and certainly silencer siRNA with Alnylam. We like that. We will continue to like that. Akash, it has to be additive to what we already do in which 1 plus 1 is 3. We do have a heightened interest in stuff than we probably had before. I think for their first growth years of Regeneron, it was not invented here.

We kind of stayed away from stuff like that. But I think with regards to how cool the technology is, we love gene cell therapy and things of that nature, I would expect us to be more and more involved in that area. And we have -- we certainly have one of the cleanest balance sheets within the pharma and biotech industry to be able to do that. We have a ton of optionality it provides.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Understood. Now I mean, one thing that is kind of notable you didn't talk about, you look at Sanofi's strategy to model like ex -- life after dupi, right? And they have TSLP and they have OX-40. They are taking multiple bets in I&I and kind of leveraging that sales force that they've been able to build over time.

You would almost call it a plan to win. Who knows? But I guess, the question is for Regeneron, right, life after dupi, how do you kind of leverage the commercial infrastructure that you guys are starting to build, the expertise in I&I that you've built? Are there any targets or any areas in that space that you find particularly compelling?

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

Yes. I mean, if the CEO was here, he would tell you that the life -- there's still a long runway for dupi. I think our composition of matter patent is 2031. And I think it's 2032 ex U.S. And I think we still have a host of indications that are coming in that space.

Sanofi has taken an approach where they are going after lifecycle management through kind of their BD approach. We have things brewing that are probably a little too early to let the public know. But it's not lost on us with regards to life after dupi and what we need to do, obviously, because we're building a pretty big I&I infrastructure, Akash, out there. And obviously, we're going to need life after dupi. We just haven't let the public know exactly what that is yet.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Understood. Now I think like one of the proverbial white whales for you guys has been obesity. I mean, this is not -- your targets that you're going to introduce over the next couple of years are not the first time that you've gone after this indication. It's something that I know is really important to your team.

The question is do you view a GLP-1 like a PD-1, right, where it's like you have one asset, then you start overlaying maybe an Activin A, maybe you start overlaying other incretins in order to get an additive benefit? But you need kind of that base GLP-1 to really be your entry into that franchise.

Do you think that -- I'm guessing you probably have some internally in development right now. But in terms of externally looking at some of the GLP-1 assets that are there to maybe speed up that process, what is the appetite for that internally at Regeneron?

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

Yes, that's a great question, Akash. And obviously, obesity is a huge category that's continuing to grow. And the GLP-1s have really changed the game there. In terms of backbone, I don't know, maybe. There's a lot to learn about how this impacts metabolism and weight over time. And we certainly are exploring those modalities and others internally at this point.

But I think for some of the add-on antibodies that we have in our portfolio, including a myostatin antibody that showed, when in combination with semaglutide in nonhuman primates, that we had greater weight loss and double the fat loss than semaglutide alone. So very promising, and we're looking to explore that combination as well as some others in the early part of '24. And that will serve as sort of a proof of concept.

And what we do with it from there, I think we'll have to figure out, whether it's continuing to partner or potentially developing something in-house. Maybe it's a bispecific that combines a GLP with a myostatin antibody, maybe it's a co-formulation, something really a lot to learn still. And that's not the only iron in the obesity fire that we have.

There's also a leptin receptor agonist that's shown some very promising data in generalized lipodystrophy and also in a patient with congenital leptin deficiency, which is a very rare disease. But it normalized an extremely obese child and made them sort of a normal weight very quickly, so a dramatic weight loss there due to this genetic abnormality in this patient.

And then finally, the genetic discovery from the Regeneron Genetics Center, GPR75, which we continue to search for the right way to target. Right now, we're working with AstraZeneca on a small molecule approach as well as internally on an antibody and with Alnylam with siRNA approach. This is the termed the skinny gene, where we sequenced -- we didn't sequence, we searched over 650,000 exomes, found around 2,000 patients that had this genetic abnormality in GPR75 gene.

And they, on average, weighed about 12 or 13 pounds less and had a 55% lower risk of being obese. So we think it's a very good genetic finding and serves as a good target. We're just trying to figure out the best way to hit that target at this point. A lot to go for obesity with Regeneron.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Understood. And maybe just lastly on obesity, I mean, I think the question I get most often from investors is, okay, garetosmab, there were safety concerns with that compound. You could even point to the Versanis/Novartis asset that's now in the hands of Lilly.

How do you think about the therapeutic window with Activin A? I mean, right, like these are millions of patients who are theoretically going to get treated with these types of medications. So why go with these assets in these types of markets? What makes you feel comfortable from a safety perspective that they'll be clean?

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

I think we have a lot to learn. But certainly, with Activin A, there's some "hair" on that mechanism, and particularly for women of reproductive age who intend to have children. So it's something that we'll need to look at very closely.

But I think with the myostatin antibody, we actually had a very benign safety profile and perhaps could serve as a better alternative. But we're going to put all of these things in man next year. And we're going to find out what kind of works synergistically in terms of preserving or building muscle while also achieving as good or better weight loss than the GLPs alone.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Okay, understood. Now maybe stepping to high-dose EYLEA -- and yes, I mean, you guys are absolutely right, very, very impressive launch. Can you kind of -- so let's start with just the clinical data. And you hit on the PULSAR data. But I don't think that, that's really well appreciated by investors, the fact that you're able to maintain BCVA. You were able to maintain these patients actually staying on these 16-week regimens.

Internally, I'm actually convinced if VABYSMO ran in your trial, I think it actually would have failed. But at the same time, you talk to all of these doctors, no one actually uses these regimens, right? No one uses the regimens that are on these clinical trials. They basically treat to complete dryness and then they start to extend over time.

So what feedback have you heard in a real-world setting in terms of how these are actually used in practice of high-dose EYLEA versus, let's say, both low-dose EYLEA and then also VABYSMO and some of the other competitors? How quickly are they able to get patients to complete dryness? And what is the kind of real-world interval that these patients are actually able to get to so far? And I know it's early days.

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

Yes. I'll preface with it's very early days. We're, what, 12 or 13 weeks into the launch here. But the early feedback has been very positive. We've seen a broad spectrum of patients using EYLEA HD, including those that were recalcitrant on very short intervals of EYLEA and unable to get dry as well as short intervals of VABYSMO and unable to get dry and have come back after one injection with EYLEA HD with much improved retina dryness and even some completely dry. So very promising early feedback.

We're also seeing switches from EYLEA with patients that are well controlled but on shorter intervals, 6-, 7-week intervals that are moving to EYLEA HD in hopes of extending the time between injections. We're also seeing Avastin switches and then even some small proportions in naive use, which is also very encouraging. So how doctors are using it? I think most of the time, they are not using the loading regimen for anyone who is not a naive patient.

They are taking the patient who's on EYLEA every 6 weeks, having them come in, giving them an injection of EYLEA HD and saying, "Come back in 6 weeks, then we'll take a look at your retina." They come back in 6 weeks. Hopefully, the retina is dry. And then they give another injection of EYLEA

HD and say, "Come back in 8 weeks." And this treat-and-extend paradigm has really been what retinal specialists have used. And that's what we're seeing with EYLEA HD in these early days of the launch.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Understood. Now I know there's been also some label changes for VABYSMO. I think there was an added warning on retinal vasculitis. Honestly, from our diligence, the absolute rate we're seeing from VABYSMO seems fairly low. I don't think that's actually concerning. But you did still get the change from the FDA on the label. So what have you seen from doc feedback about that added label warning and how that may have shifted the view of VABYSMO versus high-dose EYLEA competitively?

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

Yes. This was an update that was made to the VABYSMO label earlier this month, I believe. And it included the additional indication of RVO. But in the warnings and precaution section, it added a warning for retinal vasculitis and retinal vascular occlusion. The only other product in this category with that same warning is Beovu, which was obviously a product that had a very strong launch, but safety issues really made it a very limited use, extremely limited use today.

So obviously, the FDA felt that there was enough prevalence of these side effects to add it to their warnings and precaution section of the VABYSMO label. I think the ASRS has also kind of brought forward some cases that maybe the prevalence is a little higher than what was seen in the clinical trials. But I don't think it's something that's going to completely derail VABYSMO in the same way it did Beovu. We'll have to see though. This is something that will play out over time. And it's only been a week or 2 since the label update and the Dear Doctor letter was distributed.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Understood. Well, I guess, for my full year request, I now have to add VABYSMO on top of covering GA, so good for me. Okay. So now maybe going to the commercial market, and this is stuff that I think really matters and isn't well understood, right? You talk about, about half of the market is Medicare fee-for-service, then you also have Medicare Advantage and then you have commercial, right? And these are -- I think, for most people, they've already checked out.

What -- can you bifurcate? So like these three distinct sectors of the VEGF market, how do -- like how is the adoption for high-dose EYLEA going to differ for each one of those sectors? And what's the rate of adoption, right? It seems like fee-for-service might have much more -- much faster adoption than, let's say, Medicare Advantage or commercial. But if you could delineate between those three subsectors, it would be very helpful for us.

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

Yes, Akash, I won't get into specifics. But just so for the audience to know, I mean, Medicare fee-for-service, I mean, it's 45% of barely a franchise, right? So that's a big number. And there's no formularies associated with that, right? You come in and the doctor is going to give you what the doctor is going to give you.

And as I mentioned before, I mean, we are the category leader in that, so -- and we are finding that, that is working out fine. There are -- the payments are going through on that. And there's no issue. And we have it across all the jurisdictions in the U.S. with regards to Medicaid fee-for-service.

The next category would be Medicare Advantage. That's about 25% of the category. And there, I mean, if you looked at our charts, if Marion, our Head of Commercial, was here, I mean, we're running better than expected with regards to making sure that we get on the formularies. And we haven't found the step that is to be much different than what we're experiencing or had experienced with EYLEA 2 mg.

So that is all going well. It's probably going ahead of plan. And then the remaining is the commercial. And again, we're doing well on that front. So without getting into exact specifics on where the $43 million came from in the third quarter, we have all -- like you said, the three categories are moving along just as well as they could be at this stage.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Understood. And I know like, obviously, there's competitive dynamics here. So maybe, Bob, just generally speaking -- and this is a question I get a lot from investors as Regeneron goes into the 800s, which is do I look at EYLEA, especially in the United States, as a growth market through the switch, let's say, like over the next 3 to 5 years? Is U.S. EYLEA a top line growth story? Is it flat? Or is it down? What are kind of the internal expectations for Regeneron? And why could we actually see growth through this switch?

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

Yes, Akash, I mean, we won't give long-term guidance here with regards to that, so...

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Right. I mean, you don't have to give guidance.

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

I would just say I think the outlook that the analysts have is pretty dismal with regards to how good the PULSAR and PHOTON data has been and the start that we have with regards to 8 mg. And maybe I'll leave it at that without getting into much more granularity.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

No, that was great. Understood. Now maybe stepping back -- and you get this question, and I know you can't give any answer. So I'm going to ask a slightly different one. I call that West Virginia court literally every day, I don't know what this guy is doing. But I think one thing I do get a question on, and I just want to make it clear, like people thought you would have a decision by August. We're sitting here later in the year, and we haven't gotten one.

There are some people who ask me, "Well, Akash, does that mean that these parties are settling?" And this is a bullish interpretation for Regeneron, the fact that we haven't actually gotten a settlement. Maybe for you guys right now, just to -- I'm sure you get that question, too. Should we interpret the delay in a decision on low-dose EYLEA as something that is bullish for Regeneron or just neutral?

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

I mean, we ask ourselves that question every day. We come in and say, "Today's the day." We feel better on Fridays, right? We're going to get a court decision on Friday. And the timelines that were originally put out there by the judge in West Virginia, which was kind of late August, early September, has come and gone. And I'm sure he's doing the proper due diligence. And we'll find the answer when he's ready to kind of reveal the answer. There's nothing to make of it. I mean, we do the same thing.

We sit around, Akash, "Is this good? Is this bad?" I will say that we did put our best foot forward. And I think kind of coming out of the trial, I think people are -- the odds on Regeneron are certainly higher than they were going in. I will tell everyone the base case is that you should assume that we're going to biosimilar penetration on third week of May 2024. And that should be the base case. If we're able to kind of prevail in this trial, well, then that will be a pleasant upside.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Understood. So maybe going into dupi, and you talked about -- this is something that I don't think a lot of people appreciate, like COPD is a top 3 killer of people in the United States. Having a benefit on FEV1 is actually a very clinically meaningful outcome for patients. When you think about -- and not to mention, you have your bet on IL-33, so there seems to be a kind of a two-horse approach here.

I know this is obviously a year out, and it's maybe too soon to say. But when you think about how quick the atopic derm launch was or maybe how quick maybe the EYLEA launch was, should we draw that same analogy for DUPIXENT in COPD? It's the first biologic for a very high unmet need. What do you think the cadence of that uptake will actually be? And do you feel like maybe investors aren't appreciating that?

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

I'll take that one. I think for DUPIXENT and COPD, obviously, we need to get the results of the second study. But let's use the assumption that they will resemble at least the results of BOREAS, which where we showed a 30% reduction in exacerbations and an 83 mL improvement on FEV1 as well as an improvement in patients' quality of life. If we're able to replicate that with NOTUS, and we're going to be doing an interim analysis before the end of this year, I think there's a lot of patients that can benefit from this drug.

Bob mentioned 500,000 in the G7. There's around 300,000 in the U.S. And these, I'll remind you, were patients that were already on maximal inhaled triplet therapy. So they were sort of out of options. There's no approved biologic for COPD. DUPIXENT would be the first. And with those kinds of dramatic improvements in exacerbation rates in FEV1, I think it stands to reason there's going to be a bolus of patients that could benefit from it and the launch could be robust.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Understood. Maybe last question, and this will be on oncology. And look, it won't be on CD28. Let's just see how the safety profile plays out. But I think a lot of people -- I remember going on IQVIA, J&J's BCMAxCD3 launch has actually been pretty good. It surprised some people. And we'll see how Pfizer's drug does and the ability to give outpatient. I'll put myself in this bucket. I don't know -- when I go see ASH and I see like an 80% or 90% ORR, I'm like, "Okay, they're about all the same."

But there is this kind of evolving role of both CD20xCD3s and then BCMAxCD3s that are starting to get sharpened in the eyes of doctors. Why do you think investors should be paying attention to these drugs? They're not differentiated targets. There's not a meaningful differentiation, I would argue, on the clinical data. Maybe you could say that on the BCMA, let's see how that plays out. But why could these markets actually be bigger than what investors expect and meaningful for Regeneron?

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

So I think that both odronextamab, the CD20xCD3 that we've developed and are waiting for an FDA decision on with the PDUFA in March of next year as well as linvoseltamab, the BCMAxCD3, are each differentiated against their competing CD3-bispecifics from some other companies. Particularly for linvoseltamab, where after about 6 months of follow-up, linvoseltamab had similar ORRs to J&J and Pfizer's products.

But we know that they had -- when they had longer follow-up. And we know that with longer follow-up, these ORRs and complete response rates tend to improve over time. So we're optimistic that when we read out the registration-enabling dataset, which should be soon, that we can be at least competitive, if not positively differentiated there.

The other piece is the safety story, where we have demonstrated the lowest rates of CRS and beyond that, lowest burden of hospitalization in our trials. And then finally, the dosing regimen for BCMAxCD3, linvoseltamab, would start as weekly, extend to q2 weekly, but then after 6 months,

potentially go to every 4 weeks if a very good partial response is achieved, at that time point or thereafter, which would be an improvement over J&J's weekly and Pfizer's every other week dosing regimen.

So there's a lot of positive differentiators for linvoseltamab. I do think the bolus of the revenue opportunity is in earlier lines. And that's going to require additional studies. And we are in the process of getting those underway. So look forward to those results down the line here and think that, yes, they have a real shot of being important revenue generators for Regeneron in due time.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Understood. I think I am out of time. I really, really do appreciate it. Great conversation as always. Thanks so much, really appreciate it.

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

Thank you.

Akash Tewari - Jefferies LLC, Research Division - Equity Analyst

Thank you, everyone, for joining.
