Biogen Inc.

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Umer Raffat, Robyn Karnauskas, Unknown Analyst

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Alisha Alaimo, Unknown Executive, Michael McDonnell

Umer Raffat Analyst

Okay. Thank you guys for joining us. Pleasure to have Biogen management, really looking forward to this conversation. Alisha, Thank you for making time. I'll let you kick things off.

Alisha Alaimo Executive

Well, thank you. I think you have a -- statement you want to say before.

Unknown Executive Executive

Yes. So we will be making forward-looking statements, which are based upon our current expectations and beliefs. And these may differ from actual results, and I encourage you to consult the risk factors discussed in our SEC filings for additional detail.

Alisha Alaimo Executive

Thank you. First of all, thank you for inviting us and having us here today, and thank you for all of you that joined in the room. I know you have other things you probably could be doing, so I appreciate that you came to the session today. I think, first of all, my name is Alisha Alaimo, I head up North America for Biogen. And I think before we start with maybe the questions, it's good to sort of give a little bit of a background of why Biogen is where it is today, and what's happened over the last 2 years, which I think has been very different than the prior years.

And that was with, first of all, the appointment of a new CEO, Chris Viehbacher, who's done really a tremendous job over the last 2 years with trying to think about how do we want to sort of evolve where Biogen was.

And I think when he was appointed, it was really a perfect time for this company to start making a shift from where we were. And when you think about Biogen, all the products that we have, everything is really for a very devastating disease. Whether it's for a couple of thousand, it's a rare disease or whether it's millions for Alzheimer's, they're really hard areas to sort of break into, and so when he looked at the company, and looked at where we wanted to move forward, you have five key priorities. The first was how do we reduce our cost base. So you've probably heard over the last several quarters, he's talked about Fit for Growth.

Fit for Growth was an initiative where we end up cutting out a lot of cost. We did a bottoms-up build. Every org did. Each leader had to literally start from the bottom, go up and start cutting where we think that we could, so we could reinvest that money. That will, of course, by the end of 2025, be $1 billion in gross savings, $800 million in net.

The second thing was reprioritizing the R&D pipeline. So you saw some of the molecules we walked away from and the new sauce heavy up in. For example, recently, you saw [DAPI] for SLE. We had a readout for that. We have lidafilimab.

Obviously, [BIIB08], another molecule that we call our crown jewel, and then also we have felza. And then the third thing we did was how do we maximize our profitability. And so in the past, Biogen was known as the MS company, as everyone knows and we really looked at that portfolio and said, where do we take some of that money? We have the up on the highest ROI initiatives. So for example, we still invest in VUMERITY, which is our -- it's #1 branded oral.

But how do we then put that into the fourth initiative, which is the product launches?

And I can say even from sitting in my seat, it was literally my -- 100% of my savings went into 100% of my launches, which was for LEQEMBI, SKYCLARYS, which I know we'll talk about today, ALS and then postpartum depression with ZURZUVAE. And then last but not least, which we get a lot of questions on, and Chris has already done in the last 2 years is BD and we have a very big focus on BD, because we do know we will need to fit and feed our pipeline over the next couple of years as well. We had the acquisition of Reata, which SKYCLARYS was really a beautiful fit into our portfolio.

And then the second was high Bio, which was great for the pipeline with felza, and we believe that both of those obviously will turn great value to patients and also the shareholders. So that gives you sort of a really fast sort of view into what's happened over the last 2 years, which I think are critical, as we now look at what's going to be next for Biogen.

Umer Raffat Analyst

Excellent. Excellent. Fantastic. Well, that's a great overview. Maybe I'd love to perhaps kick things off on the LEQEMBI side.

And I think for a while, at least in my mind and for a lot of investors, it looks like LEQEMBI just going absolutely nowhere. But it looks like sales numbers are now starting to look like we're putting up some numbers on the board. So approaching, I think, almost $300 million run rate now on a global basis. And there's a lot of layers to appeal there. But maybe first, which is the part that's surprising me a little bit is the Japan number coming in really strong.

How do you -- I mean, I realize that's not what you guys are commercializing. But I guess what feedback are you guys hearing on that dynamic and the momentum there?

Alisha Alaimo Executive

Yes. Thank you for the question. Well, first of all, Biogen does have a field force in Japan as well as [indiscernible] there.

Umer Raffat Analyst

Alisha, marketing can be there?

Alisha Alaimo Executive

So we do have a field force there. So we did launch in Japan. And I think Japan is fascinating. First of all, it is an excellent launch. I think you saw the sales like double from quarter 2 to quarter 3 this year.

And there's a couple of reasons for that. First, it's a single-payer system. So once it's approved, it is paid for -- very different than what you see in the United States, which I can give you all of the challenges that come with the multi-payer system here. And then secondly, they have these appropriate use guidelines. They have these guidelines that are very specific, where they will lay out exactly what patients can get the product and how you have to diagnose and treat them.

Now I think -- if you were to hear that first blush, for example, if that happened in the U.S., you'd say, "Oh, that could be very restrictive to a launch. Well, actually, it's made it very clear, it's given them a blueprint and it's moved patients very quickly through the diagnose and treat phase. And they've done very well. And so the Japan launch is off and running, and we think that it will still continue to be very successful.

Umer Raffat Analyst

Outstanding. I guess if there's one thing, Alisha, I want to clarify on the Japanese launch, Eisai showed some slides on the patient backlog that was ready to go in U.S. and the patient backlog ready to go in Japan. And I think what they were implying was there were 6,000 patients still waiting for treatment in U.S. and 4,000 are on it.

But on the Japanese side, it sounded like there's about 6,000 or so of which only 500 are still on the wait list. And when I looked at that, I was like, does that mean Japanese was a big bolus effect, we're kind of benefiting from that, but the momentum will be a little more gradual from here? Or is that not consistent with your understanding of the market evolution?

Alisha Alaimo Executive

So I think that they're still going to have good growth as they move through their launch. I think with a launch where you have a single-payer system and you have centers of excellence. Basically, there's always going to be a bolus. You see it in rare disease, you see it anywhere where you have to go to the center. We sell with SPINRAZA.

We sell SKYCLARYS. I think though, now though, it will be about how do you get those

community doctors to filter in those patients into those centers to get treated. So I do believe that they will still have good growth. And as far as the 6,000 in the U.S., you have to look at where those numbers come from. Those numbers are not exact, and you have to go to every single office to ask those questions of how many patients are waiting.

I can tell you, I was out in the field just 2 weeks ago visiting physicians actually in Florida.

And the number of patients they say that they have waiting are massive numbers, right? So the waiting -- the patients waiting, it changes literally by the minute and by the day. It depends on who's referring to which center and who's treating. And so I would say, when I take a step back and I look at launches no matter what country they are in, the biggest thing you have to have is the awareness for the physician to drive that patient into the office. And if you sort of crack that, you're always going to have a line of patients waiting for the product.

Umer Raffat Analyst

Alisha, is there a scenario that in 2 to 4 quarters from now, Japan exceeds U.S. in terms of size? Is that possible as you're modeling it off through?

Robyn Karnauskas Analyst

So I'm not close to Japan, but I would say they better not be. Revenue and our patient numbers. So I think Japan will be very successful. But from what I see in the U.S. and the numbers that you look at, even all the leading indicators, I just saw the last 2 months of the blood-based biomarkers being used, the PET scans being used, everything keeps accelerating.

And so the U.S. is just going to continue to grow and compound. And to be very explicit about it, there aren't as many doctors as we still need prescribing the drug. The runway in the United States is huge. When you look at the number of neurologists that can prescribe in the numbers that are prescribing today.

And even when you look at the depth, half of the doctors that are writing have still only started with 1 or 2 patients, so they still have a long runway even in those offices. So the runway in the U.S. is huge and the patient population is very large.

Umer Raffat Analyst

Got it. So -- okay. So maybe just dialing down the U.S. side a little more. You said runway is huge, dockside 1 to 2 patients.

Are you hearing that significant expansion is coming. They want to do more is just the bottlenecks in the system holding them back. Is that what you're hearing? Or is that an aspiration given that Alzheimer's is large, so it should go down that direction?

Alisha Alaimo Executive

So this is a really -- this market, we've had to build this market. It started back in the day with [indiscernible]. So we knew what we were getting into. And I think first and foremost, for those physicians that have really started from day one, I have to give them a lot of credit, and I have to thank them, because it is a lot of work. And I referred to the fact that I was in the field just 2

weeks ago and I'm sitting across the desk from these physicians saying, well, what is it?

What are you struggling with? Or why does it take so long? And he looked at me and he said, "Do you understand how much work it takes to diagnose the patient. It's not about prescribing the drug.

It is how long it takes to make sure you're diagnosing them appropriately, and he said it takes a lot of time and effort, and he said, we just have to get through that, for every single patient. And so in some of these large IDNs that have hundreds of patients now on product, they are well-oiled machines. So the bottleneck or the gating that people ask about will be different for every office. I will say the biggest part, and we call it infrastructure, but that infrastructure is different for each physician's office. And so when the -- the doctor said it's a heavy lift.

I said, "Well, what are you -- what is so heavy for you?" And he said, "The biggest plan in my area is I have to do a CDR summer boxes". He goes, that's done in clinical trials, right? That's one little thing, but it's the majority of his plans. And so he has to figure out what staff can do a CDR summer boxes? How do you understand how to do it.

His issue is not infusion. His issue is not pet. It's how do you get through sort of those first tests. In some areas like you'll hear about a large IDN where they have hundreds of patients on and they'll say, "Well, we're now running out of chairs", right, for infusion capacity.

You can go to an outside AIC, except that IDN may not permit it because they want to keep those infusions within their network. And so then it becomes a negotiation on do you open up more chairs into just an extra sort of room? Will they let you temporarily go to an AIC, can you negotiate chairs with oncology. And so you see that every single one of them is just a little bit different, but, what we also see in our market research, is if a patient comes in and asked for it, the grant rate is very high. So a doctor will say you asked for it.

I'm going to help you get on it, even if they think that it's a heavy lift.

And so a lot of these doctors that are going through 1s and 2s, we have seen that a lot of times the patient really wants to own the product. And so they do it, they start getting through it. Once they get to sort of 5 or 10, they start moving much more quickly.

Umer Raffat Analyst

Got it. So -- and I know subcu may happen in due time as well. But let's hold that for a second. Based on the offering today and blood-based biomarkers, there's more adoption right now. I know you guys went from like about $30 million in U.S.

to about $40 million. Is that the cadence you expect? Is that the momentum, additional $10 million per quarter type of addition?

Alisha Alaimo Executive

I think that it will continue to be linear. We've seen some puts and takes. Like in the summer time, everyone asked, oh, is there a summer effect -- we won't know that until you get literally probably 2 years under your belt to see if there's sort of a -- we call it the snowbird effect or a lot of patients flying back and forth trying to find their infusions. But then like I look at

October and November, and I'm seeing very good numbers, right? So it's -- I think it just depends on timing.

It depends on when these sites come online. It depends on when some of the depth comes with the physicians. So I would say, to be safe, I would expect a linear trend at this point, until some things sort of change in the market.

Umer Raffat Analyst

Okay. Got it. And one dynamic we in the back on line, I'm a little nervous about is, because it's not symptomatic benefit per se, it's a benefit that sort of cumulatively really starts to add up, but patient doesn't know it immediately if something changed for them or not. Are you guys seeing any preliminary evidence on duration of therapy, where people have been operator and now I'm going to fall. Is there any dynamic like that at play yet?

Because so far, it's all about incident patients, so I'm just curious about directional therapy.

Alisha Alaimo Executive

So no, we're not seeing that yet. I would say any discontinuations would be similar to what we saw in the trial. And you don't have a ton of patients sitting in that year mark yet. What we are seeing, though, and it also now is showing up in our market research and even when I was talking to some of the KMEs, the 6-month mark seems to be an interesting mark for physicians, because that is when patients tend to, and this is based off of qualitative speaking. They tend to come back and they start recognizing their differences.

And every patient has a different thing that they will say that they have seen an improvement on, or something has changed, the caregiver will notice a change or a child will notice a change and the parent. And that is when the doctor goes, it's working. And that's when we start seeing them accelerate more prescribing. So it's been interesting because as soon as they have the real-world experience, they get the feedback from the patient. You see them then diagnosing and treating more.

You also see them talking to peers more -- and what we've noticed with some of the physicians who've also accelerated as they're getting feedback from peers on the patient experience.

Umer Raffat Analyst

That's actually very interesting. I do remember the curves on this. I guess what percent of doctors have patients that are hitting that time point? Do we know -- I realize it's very broad.

Alisha Alaimo Executive

That's broad.

Umer Raffat Analyst

Or what percent of patients -- what's the median duration right now across the patients on commercial therapy? Do we have a sense -- is it sub 6 months?

Alisha Alaimo Executive

It depends on when they've come on. But if you think about those IDNs, so just to put in perspective, from the first day they decide to prescribe it took an idea in 8 months to get first patient on board. So I'm going to have a lot that are coming into that 6 months, a little bit over a 6-month time period.

Umer Raffat Analyst

Between now and March?

Alisha Alaimo Executive

Yes.

Umer Raffat Analyst

Because we have a lot more in the 6 months, I think. Okay, excellent. And then I guess that maybe takes me into the subcu dynamic. Is the chair issue in terms of infusion, a huge deal as it relates to getting -- like are you hearing that patients are unable to get it, because of that share issue? Because I'm just trying to quantify, could subcu inflect?

Or are we still thinking this linear $10 million a quarter type of increase? Or would subcu inflect that?

Alisha Alaimo Executive

So to answer your first question is a patient getting to a chair, an issue. And I'd say my overarching answer would be, no.

I'm going to put a caveat on that, though. However, sometimes are drive times too far for them or sometimes is that putting a burden on them, yes. However, now in the Northeast and the Southeast and the Midwest, we've had very large AICs now put LEQEMBI formulary, and we've now opened up many chairs across the country. Where, for example, we have a cohort of patients that were always going into New York City. They now can go to Brooklyn, Queens.

They have much more local options Long Island, than what they had before. Same in Florida. They are going to these large centers, now it's more closer to home. And so the chairs aren't necessarily the issue. I think that where IV maintenance and subcu come into play.

First of all, optionality for patients and physicians are always good because like I said, no office is the same. Physicians do love seeing the patients, I think, upfront and in person for their IV, especially in those first 6 months and rather monitoring for ARIA. But then if you were able to remove the plaque and go into an IV maintenance phase where it's only once a month, that again alleviates the burden on the patients. So I think that is a great option. If they can go to subcu they don't have to travel, which we don't know yet what that label is going to look like.

We don't know if they'll have an option of either doing it at home or going to the physician's office, but not traveling then becomes excellent for them, and then for induction subcu. That is where it will be interesting to see how do physicians react because right now, they're very

used to doing the IV. So we'll see what happens once we get the label, but the subcu induction becomes important, because if a patient finds that to be much more convenient, they don't want to go in for an IV, they have that option. And so I think all of those things will become important to launch.

Umer Raffat Analyst

I guess is your base case that you'll get a label where you don't have to -- you can do it at home?

Alisha Alaimo Executive

I mean...

Unknown Executive Executive

That will be the aim.

Umer Raffat Analyst

We hear back -- I think 1Q, is that right?

Unknown Executive Executive

1Q for maintenance subcu, correct.

Umer Raffat Analyst

What is the subcu induction timeline look like? .

Unknown Executive Executive

So on that one, generating data to support a lower dose, which we've said we think there's a potential to utilize a lower dose based upon the overexposure that we saw the initial data presented at CTAD in '23. So we're looking at that lower dose generating the data. We haven't guided towards the timing of a filing -- but we have Eisai as a regulatory lead has guided towards a potential regulatory decision by the end of their fiscal year '25, which is ultimately the end of March 2026.

Umer Raffat Analyst

Okay. Got it. So maintenance subcu, we found out in 1Q, '25 inductions sucu 1Q, '25?

Unknown Executive Executive

Sorry. So maintenance IV is January '25. The filing for subcu maintenance. So again, after an individual has gone through a certain period of IV and remove the plaques. That rolling submission was completed at the end of October.

The FDA would have up to 60 days to decide -- to review the filing and decide whether to accept it, once accepted, we would expect to get the review type, whether it be standard or priority. So somewhere, depending upon the review type would put a regulatory decision around midyear, give or take.

Umer Raffat Analyst

Oh, maybe year. Okay, got it. So -- so there's a midyear date for the subcu maintenance. IV maintenance is January '25 and subcu induction could be 1Q '26?

Unknown Executive Executive

Correct. .

Umer Raffat Analyst

Okay. Excellent. Mike, anything else you want to touch upon subcu?

Unknown Analyst Analyst

Yes. Before we depart from this. I just want to go back to...

Umer Raffat Analyst

The timelines on this, I have to admit, have dragged materially long. I remember talking to Priya about this here last year, and we were still sort of talking about how induction might involve a slightly different strategy than maintenance. But it's taken a little longer. But conversely, it looks like the market development was sort of taking its own time anyway.

Unknown Executive Executive

And part of that was the fact that the original data presented for subcu was that 720-milligram weekly dose and that was in treatment naive individuals. And as I said earlier, we saw an overexposure, so actually additional plaque removal as compared to the 10 mg per kg biweekly. So that for treatment initiation, we wanted to utilize a lower dose for maintenance after the amyloid have been cleared. And there, we needed to ultimately go ahead and generate 3 months of immunogenicity data, in order to support the filing of that is more of a kind of check-the-box exercise for the commercially proposed dose. So we needed some time even for the maintenance to go ahead and generate that data to support the -- and complete the filing.

Umer Raffat Analyst

Got it.

Unknown Executive Executive

Right. I just going to say just talking back to Eisai guidance. Eisai has a nice slide that says the performance of Americas Pharmaceutical business. And for our fiscal year '24, they're guiding to JPY 26.5 billion, which kind of implies like a 65% growth in the second half compared to the first half. So in the first half, they did JPY 10.5 billion to get to 26.5 million, they need to do JPY 16.5 billion in our fourth quarter in next year's first quarter.

And I'm thinking what you said about how a lot of these patients will kind of hit their 6-month mark pretty soon. Is that we'll get them there to that extra $1.5 billion to hit their guidance?

Alisha Alaimo Executive

I think that, the acceleration, which you'll see, obviously, going in Q1 of next year, there's going to be many things coming into play. I think one was getting a lot of these AICs on board, right? We opened up a lot of infusion capacity. Through getting LEQEMBI on the formulary. I think secondarily, one KPI that I look at quite a bit is how many new writers come on board.

And that becomes really important for LEQEMBI because, number one, again, there's a long runway. And if you look at Q2 to Q3, we had a 40% increase in number of new writers. But remember, when they come on, they only do 1 or 2 patients. for like 6 months, right? And so what you will start seeing then is, do they start getting depth?

So if you already have the writing and setting up infrastructure, getting that depth becomes a lot easier. And so that will also become an accelerating factor.

Umer Raffat Analyst

So Alisha, is it your expectation that the current linear trend of $10 million in sales at per quarter could be $15 million to $20 million as we -- at some point next year?

Alisha Alaimo Executive

I mean we would, hope so.

Unknown Executive Executive

Yes. I wouldn't guide at this point.

Alisha Alaimo Executive

We're not going to guide, but...

Umer Raffat Analyst

But aspirationally.

Alisha Alaimo Executive

My aspirations are larger than the numbers we probably guide to, right? And as a commercial leader, they kind of need to be to push the teams. But -- at some point, these systems need to come on board and move, and it is going to take some time. And I think with a competitor out there will help as well, by the way, However, at some point, these patients need to move through.

Umer Raffat Analyst

Got it. Part D, would you be able to get Part D reimbursement on subcu?

Alisha Alaimo Executive

So, you know...

Umer Raffat Analyst

So if it's at home, if that's the label that comes through?

Alisha Alaimo Executive

So Part D, right now with Part B, I think everyone knows it's actually pretty good across the board. We have very good coverage across the board for Part B. Part D is a different beast as we know. And so there, you become -- you need to go and negotiate all of your individual contracts. We, of course, believe at this point, we will get Part D coverage.

But now with a new administration, with the IRA. We're also looking at what things are changing. I think what works for us right now under the current IRA is that the patient out-of-pocket costs are going to be much less, right?

So Part D becomes a very attractive option for patients. But remember, as with Medicare, Medicare is overnight, you get reimbursement, it's done Part D, you do need to negotiate through [indiscernible] players and everything right Yes. So we would have to start that at least -- it's not an immediate inflection, because you do need to get access through those plans.

Umer Raffat Analyst

Got it. Okay. Got it. Excellent. Mike, anything else on the limb side just before we move on because I know there's other topics.

Okay. Excellent. So maybe let's transition quickly now to some of the other programs. SKYCLARYS. I think right around $300 million sales run rate.

And it looks like, I think going from 1Q to 2Q to 3Q, there's been some -- like there's a lot of growth from 4Q to 1Q, and I think since then, there's an expectation that the launch has tempered a little bit. Could you just walk us through the dynamics there? And -- are we still on path towards a perhaps $1 billion product? Or is it something a little more lower than that?

Alisha Alaimo Executive

So SKYCLARYS, rare disease, Friedreich's ataxia. We've learned a lot since we obviously acquired Reata and working in this space. And I think what you saw in the beginning in the launch dynamics is you have a cohort of patients who were diagnosed knew they had it, ready to go sitting at centers of excellence. And that was a large -- it took a lot to work through the long line of patients. And you have some super users out there in the country, who just knew like we have one doctor who claims is 250 patients, right?

So they really just moved through these patients. So now that we got through the majority of the bull, I can say, I still have a cohort that we're working through now. The majority of my new patients that are coming on to product is one doctor, one patient. And they don't know they have Friedreich's ataxia.

In fact, when my team goes in to talk to them, they'll say, we believe you have a Friedreich's ataxia patient, and they say, what is Friedreich's ataxia. So that is where we're at now. And so what we have built, I have 3 teams that one hunts down leads, a second goes down and chases them out in the field and the third works in my COEs. That -- those teams are fed by an AI engine where we're able to take all of the electronic health records over the past several years. We know which doctors these patients, it's obviously identified where the patients go

to -- and then we have phone calls.

I mean they're making 60 phone calls in a day, a team of them to physicians, just to try and find where these patients are sitting, and then we send in the field.

And so -- now they're also slower progressors. So even when the physician calls the patient. The patient will say, "Well, I'm kind of doing okay. I'm over the age of 50 -- I'm kind of okay" and the doctor say you should come in and see if you are Friedreich's ataxia. There's now a product for you and it could fill your progression.

And so that obviously takes time. These people are working, they're with their families and they've got to take time to come in, get diagnosed and decide if they want on the treatment. That is why it shows that we have sort of slowed. It's the finding the pulling the patients in. However, on the flip side, again, we still have good runway.

So we still have ambition in making this a $1 billion product. It just takes a little time to get there, but we add patients every week, we add patients every month, we add patients every quarter. And you'll see puts and takes in some of the numbers. We've been asked a lot about [discons], right, like we're using a lot of patients [discounting]. And it's no different than the MOX trial, but what you don't see is some of these patients stop because they may have an elevated liver enzyme, but they eventually come back.

They may come back at a lower dose, but they do come back, right? So it's not a true discon in that sense.

Umer Raffat Analyst

Got it. What's the target population again? In terms of prevalence pool in the U.S.?

Alisha Alaimo Executive

4,500 is the epi number. And 5,000 was -- the total Epi-500 of those are under the age of 16. And so the other thing that will give us a good boost is once we complete the trial for pediatrics.

Umer Raffat Analyst

Got it. I remember last time you guys disclosed patients on therapy. I think you guys had 1,000 patients that was 4Q last year. Sales are up 50%. And so, is it reasonable to assume we're kind of like in the 1,500 patient range?

Alisha Alaimo Executive

I think it's reasonable to assume that, we've had great market penetration. We still have the best market penetration out of any rare disease drug. The problem with guiding to patients is what I had just said to you, where some will stop, and they come back. So we have a lot of puts and takes in this patient number, which makes it a little inconsistent.

Umer Raffat Analyst

So Alisha, is there a world in which where we could say, 2,000 may have started, 1,500 are on

it. So you've kind of hit close to 50% penetration already at some level. Because when I hear 50%, I'm thinking you're starting to get to an upper limit of what the realistic penetration could look like?

Alisha Alaimo Executive

Yes, except for our penetration is basically the patients that we know have had a start form and are still on drug. So we -- it's about how we've maintained them.

Umer Raffat Analyst

Okay. Yes. Got it. Is it realistic to assume 75% peak penetration type of thing? And then we obviously have to adjust for how many are realistically on the drug?

Alisha Alaimo Executive

I typically don't guide to that. I think, though, if you look at benchmarks and you look at what happens. 70% is usually around the benchmark that you see for penetration. Look at SPINRAZA. It's been on the market for 8 years.

Two other competitors, and we're still getting new patients. We're still finding new patients that we didn't know were out there. So it will move, and I think we're going to see that -- as with most rare disease launches, those numbers, the epi numbers do change eventually because more patients discover that they have.

Unknown Analyst Analyst

[indiscernible], you kind of preempted my question. I was going to ask you, to what extent could SPINRAZA be used as a revenue comp, as we could try to model this launch, rare disease kind of you found out more -- that there were more patients that initially anticipate with SPINRAZA. Could this be kind of a reasonable comp to SKYCLARYS, or no?

Alisha Alaimo Executive

It is only in the fact that we look at the market penetration. But for example, as of -- if I compare launch to launch, we're beating the SPINRAZA market penetration. And SKYCLARYS will not have really a true competitor the way in which SPINRAZA did. And so that also helped the two competitors came in and took over the market, but they also took some of the patients, right? So that was part of the problem.

Umer Raffat Analyst

Got it. I should know this, this is just U.S. sales, right, the $300 million that we're discussing right now, the run rate?

Michael McDonnell Executive

Global.

Alisha Alaimo Executive

It's global.

Umer Raffat Analyst

This is global sales. I see.

Alisha Alaimo Executive

And we're now in over 15 markets outside of...

Umer Raffat Analyst

How much is U.S. of the $300 million?

Alisha Alaimo Executive

So we will be 50-50, eventually right now, where the majority of it because Europe is getting online. But Europe is growing actually quite quickly.

Umer Raffat Analyst

Okay. Okay, excellent. Excellent. Maybe transitioning very quickly also to ZURZUVAE. Am I saying that right?

Alisha Alaimo Executive

You are.

Umer Raffat Analyst

Excellent. Next phase of growth, I think you talked about it. Could you just remind us what that is?

Alisha Alaimo Executive

ZURZUVAE has been, I think, for a lot of people a pleasant surprise. We had really planned on launching in MDD. We really built an amazing, very well-thought-out plan on that launch and then ended up with the PPD label, which I think people in the beginning were disappointed by, but the first ever indicated product for PPD and as a 14-day treatment. It's very appealing, especially to mothers who don't want to be on a drug long term. And so what we've seen is this drug has actually taken off quite well, very little resourcing.

We were very mindful that we didn't plan for PPD. And so we put not a lot of resourcing behind it. We went out very thoughtfully with Sage. And in fact, we got a couple of things wrong. We thought that the the psychiatrist would be our big writers.

In fact, if you look at prescription data, we'll show that, and it will show that they write a lot for PPD. In reality, they actually don't. The OB/GYNs now have taken over as really our major prescribers, and we now fast forward to today, we thought OB/GYNs may write one prescription every now and then. But now like 2/3 of them are doing over 2 prescriptions, since they've written and so, we're seeing that they're actually getting a good depth. We also see that in these large practices, it is much easier to grow this product, than when you go to the single doctor single practice like you did with some of the psychiatrists.

And that is because -- you never know in the OB/GYN practice, who is actually seeing the PPD

patient, it might just land under a prescription under a certain doctor, but all of these docs are seeing it. And so you've seen an acceleration in our launch now the last two quarters.

And that's been a lot, because of these OB/GYNs have had depth in their office practices. So we've now decided to expand. We will be expanding the field force. We have posted the roles. We now have a little bit of a tweak to our go-to-market model.

And so now us along with Sage -- we'll be expanding by January 1. Sage actually did their expansion as of October 1. We're now coming online January 1. And -- and you will now see us increase our reach and frequency, especially with the OB guys and the writers, we now know much more for next year.

Umer Raffat Analyst

Got it. Excellent. Maybe just continuing down some of the additional topics I wanted to make sure we touched upon. VUMERITY. My understanding is 2033 is where you guys have a rise until on the IP side.

Is that right? Or is there any generic settlement or anything that we should be aware of prior to that?

Michael McDonnell Executive

Currently, we have three Orange Book patents each expiring in 2033, there is Zydus. -- they so ultimately, Biogen last year filed a complaint agencies on the basis of copyright infringement. That trial is currently set for July of 2025. Biogen regulatory approval of Zydus' generic product is stayed until we have the outcome of that trial. But that's probably all I can comment, in terms of ongoing litigation Alisha, I don't know if you want to say anything about VUMERITY broadly?

Alisha Alaimo Executive

Yes. VUMERITY is one of those products that we decided to put more money behind. In fact, this year, it's performed very well. We saw good growth in VUMERITY so far. It's the #1 branded oral doctors really like it.

And also keep in mind, there's a lot of generics out there, especially for TECFIDERA, but doctors and patients also love the patient services that come along with prescribing some of these products. And so VUMERITY actually turned out to be a very good product for us. And so we have put more money behind that.

Umer Raffat Analyst

What's the main patient service that stands out. On this?

Alisha Alaimo Executive

I mean we do kind of everything in patient services from getting the start forms put through benefits investigation. They call and asked questions about the product. It's it's -- they end up having sort of their own case manager in a sense that they have a relationship with that they can kind of troubleshoot and the case manager can troubleshoot through the offices for

them.

Umer Raffat Analyst

I see. Okay, got it. OCREVUS, what's the expectation of biosimilar entry for you guys? .

Michael McDonnell Executive

I would say it's hard to speculate on the exact timing of biosimilar entry. I mean, with that being said, we do expect that Genentech would be entitled to the 12 years of regulatory debt exclusivity per FDA regulations. With approval of biosimilar our royalty -- our tiered royalty structure would be cut by 50% -- over-- think the important thing to note here as well is that Genentech is moving forward with different life cycle management initiatives. They got approval for subcu OCREVUS. They also have a high dose they're evaluating.

So ultimately, we do believe that those can help protect and extend the franchise versus biosimilar competition. But in terms of kind of specific entry, timing of entry of biosimilars and sales guidance, Genentech is solely responsible for development core.

Umer Raffat Analyst

But would you agree consensus miss models, OCREVUS in the sense that consensus has like a biosimilar erosion being modeled, whereas from a royalty perspective, there's a 50% cut regardless of all those initiatives, the data first passengers.

Michael McDonnell Executive

So per the contract, there would be a 50% cut to the tiered royalty structure upon the approval of the bios.

Umer Raffat Analyst

And that should equate to 50% sales cut to Biogen correct?

Michael McDonnell Executive

If sales remain the same depending upon the specific tiers, it could.

Umer Raffat Analyst

Got it. And then also just to clarify, if the trial for Gazyva in lupus nephritis hits, you guys get a royalty on all of that, right, because you're on the molecule?

Michael McDonnell Executive

We do. So across indications, our royalty would remain intact in profit.

Umer Raffat Analyst

Okay. Which actually brings me to sort of like a bigger picture question then. It looks like Biogen is making a pretty significant investment on the lupus side. It's a question I brought up on the earnings call as well. But if I just go in a silo and ask myself, where are we seeing the most compelling lupus data envelopment?

It looks like the B-cell depletion approaches at least on early data show very remarkable permission lupus. And that happens to be the pocket where Biogen is sort of not investing a lot of time. So I'm just curious how are you guys thinking about that? Or are you limited in going there because of some of the Roche collaboration on [indiscernible]?

Michael McDonnell Executive

I haven't called out any limitations. I would say with the B-cell depleters, obviously, we've seen some encouraging data, small patient numbers. With that being said, I think there are some questions around in terms of long-term durability of response. What that looks like. And that's something that obviously the data will suss out over time.

Really, specifically for us, I think we're encouraged by DAP for a few different reasons, so our CD40 ligand. I mean we saw what we view to be a competitive response on BICLA, which is obviously a registratable endpoint. But then beyond that, kind of understanding the treatment objectives that physicians have in the real world, trying to prevent that breakthrough disease activity in terms of flares, and be able to reduce the high dose of corticosteroids.

These are endpoints that we've constructed to be able to understand the clinical profile of DAP. And we're seeing consistency across that which gives us -- which encourages us to believe that if approved, is going to be an important product for patients. The other thing I would point out in terms of CAR-T is that it's not easy to do from an operational [indiscernible].

Umer Raffat Analyst

No, Car-T sure.

Michael McDonnell Executive

So in that sense, obviously, we'll see if that might be reserved for a subset of patients, those that are refractory, for instance. And then should there be a more bispecific, for instance, in terms of B-cell depletion. I mean there I think we're even earlier in terms of data, so we'll have to see what that shows us as well. We feel good about the clinical profile we've seen with that.

Umer Raffat Analyst

If Roche hits the Gazava trial in lupus next year. I guess how does that change the dynamic versus your DAP launch? And how do you guys balance the two?

Michael McDonnell Executive

Yes. So we would have to see ultimately. I know they've gotten good results in lupus nephritis. With that being said, lupus nephritis is a more specific indication. So we'll have to see how the B cell approach is -- plays out in kind of a more broad SLE, where you may have involvement of different and multiple organ systems.

But again, we'll have to wait to see how that data plays out.

Umer Raffat Analyst

Okay. Got it. And -- and this is -- I think you may have heard me bring this up as well. Is there any chance under the new RFK and the presume that somehow your first Phase III forms the basis of a very early approval in lupus and Alisha having more work to do?

Michael McDonnell Executive

So it's a good question. I mean, we've been saying for some time now that our expectation -- our current expectation is that we're going to have to run the second trial we're planning to do that this year.

Umer Raffat Analyst

Are you guys attempting any conversations in D.C. towards this?

Michael McDonnell Executive

Engagement with the FDA will be ongoing. We do that for any Phase III program that we can do. But I guess, to underscore right now, our current expectation is we'll run the second trial to support a filing.

Umer Raffat Analyst

Okay. Mike, anything else on lupus just before we transition on, we have 1 minute and 40 seconds.

Michael McDonnell Executive

No.

Umer Raffat Analyst

Perfect answer. All right. Felzartamab. I want to touch up on this program a little bit. So -- in terms of the duration of response, I noticed the three relapses after stopping therapy at 6 months.

How should we think about those? And in general, how should we think about other CD38 programs replicating this type of data set?

Michael McDonnell Executive

Yes. So I think the one important thing I'd point about the kind of the remission -- the loss of remission, that's specifically in antibody-mediated rejection. So that's in a situation indication, where you're receiving non-self organ. That is the -- across three indications where we currently have proof of concept. That's the one we're seeing kind of a rebound of the response.

So if you look at again, for instance, if you look at primary nephropathy, there, you're having from that 6-month 9 dose treatment regimen, you're getting a prolonged response out to 2 years. So in AMR, the one you're citing, we did see kind of features of rejection beginning to return at the 1-year mark that we didn't see from -- at the 6-month mark. And there, this is something where we believe additional doses may be necessary in that specific AMR indication. And right now, we have -- we're designing a Phase III that can accommodate some

of that retreatment paradigm, so we'll look at that there. And in terms of other anti-38.

Right now, we believe we're leading with the anti-CD38 in the autoimmune indications. Felzartamab specifically has specific epitope that allows for the specific depletion of those plasma cells and plasmablast ones generating those auto antibodies. So with that being said, the mechanism by which we're doing that is not dependent upon complement-dependent cytotoxicity, right? So that gives us some potential to see a reduced infusion-related reaction benefit versus the approved therapies, as well as shorter infusion times. But on top of that, obviously, we'll look to see what the Phase III data shows us as well.

Umer Raffat Analyst

Got it. And then finally also, ITP, was that an indication you guys would consider? I know there's some interest in that space in general?

Michael McDonnell Executive

Yes. So we have characterized felzartamab as a potential pipeline and a product type approach. So in indications where we believe that an anti-CD38 approach makes sense, it's something we could certainly explore. In ITP, we have seen some very early data with an anti-CD38 approach showing some encouraging results. So it's something that we're thinking about, but the felzartamab team right now is looking at different life cycle initiatives, including where other indications we might make sense.

Umer Raffat Analyst

Excellent. Listen, thank you that so much for making time. It's great having you.

Alisha Alaimo Executive

Thank you.