Biogen Inc.

Biogen Inc. presents at J.P. Morgan 42nd Annual Healthcare Conference 2024

Monday, January 8, 2024 2:15 PM

Event Participants

Analysts 1
Christopher Schott

Executives 1
Christopher Viehbacher

Christopher Schott Analyst

So good morning, everybody. I'm Chris Schott at JPMorgan, and it's my pleasure to be hosting a fireside chat today with Chris Viehbacher, who joined Biogen as CEO, I guess, a little bit over a year ago. So Chris, happy New Year. Thanks for joining us.

Christopher Viehbacher Executive

Happy New year to you too, Chris.

Christopher Schott Analyst

Yes. So I think we were talking before. About a year ago, we were sitting in these same 2 seats. You had just come on as CEO. So I would love to start the conversation with just your reflections on how the last year has gone, anything that surprised you at a positive or negative in the CEO seat?

And we'll kick off from there.

Christopher Viehbacher Executive

Well, thanks, Chris. Yes, it was a busy year in 2023. A year ago, we were still, as a company, kind of still under the cloud of ADUHELM. We've been declining already for 3 years. We've talked about our melting iceberg of the MS franchise.

A lot of investors had said, "Well, you've got a fairly mature product portfolio. Why is your cost base so high?" So I think last year, I said our objective is really return to growth. And obviously, that's important for investors, but it's also important inside the company. A company that is declining year-on-year, it's how do you get motivated? And all your business metrics don't really work all that well because you're trying to do less bad.

So we outlined 5 things that we thought were going to be important. One was we had to shift the whole focus of the company from MS to new growth drivers. And that is actually not that easy. We've been doing MS for 45 years, and there are an awful lot of relationships with physicians and patients. And yet, unfortunately, we don't have a new medicine to launch, so we needed to move towards LEQEMBI, and, at that time, zuranolone.

Well, LEQEMBI, of course, has had not only accelerated approval, we got full approval, then people were concerned around CMS. CMS came through. The registry hasn't been difficult. We always knew it was going to be a slow ramp because this is such a pioneering activity. And on zuranolone, of course, we only got postpartum depression and not the MDD.

But I think even postpartum depression, obviously, huge unmet need, massive media interest, and I think we're off to a good start with the launch. Second thing was we said our R&D pipeline had an awful lot of things in there that didn't really make any sense. So with Priya's help, we went through and really weeded out a number of projects that were costing an awful lot of money but didn't have an awful lot of value. The third one was to look at our cost base. And we didn't just do a cost reduction exercise, we decided to completely redesign the company.

We said, what do we need to be successful in 2025 with the products we have, with the research and development we're doing? And let's build that company and then basically manage out the other aspects that weren't going to contribute in the future. And so we announced $1 billion of gross cost savings with about $800 million net. We also had a couple of products that people had taken the -- were not paying as much attention to, VUMERITY and SPINRAZA. I mean if you looked at analyst forecast, they had -- well, SPINRAZA is going to decline, there's a gene therapy, there's an oral, oral always beats an infusion.

Well, the reality is that the more serious a disease, the more efficacy matters. And I think that's what we're seeing, and we put new energy behind both VUMERITY and SPINRAZA, and we're seeing those products stabilize and even growing. And then we really also had to look at what else could we do outside the company. We needed more for growth. And we started an exercise early in the new year and did the Reata acquisition in August.

That's actually financially good because now that we have European approval, we can certainly say that the IRR is greater than WACC, which is not necessarily something you see every day in M&A in our business, but it's hugely important strategically for us. So now I think we're actually well positioned to return to growth, and I think we're in a much different place than where we were a year ago.

Christopher Schott Analyst

That's great. When I think about those kind of challenges and opportunities of the company, where do you think you've made the most progress? And where do you think there's still the most work to do?

Christopher Viehbacher Executive

Well, in business, it's always easier to do restructuring. So we're certainly well ahead on the cost savings. We've done a great job, I think, of really getting our R&D focused. It's a lot harder

to build and grow. And so I think this year is really about execution.

We've got all of the elements that we need. LEQEMBI, I think, we're seeing some really good progress on that launch. But we're just launching PPD. Our team was just out in the field as of last week. SKYCLARYS is off to a very good launch.

We had something like 25% of the entire population on drug by the end of last year. And -- but I think we also have to think about the pipeline. I'm going to spend an awful lot of time on our pipeline. We have a lot of very interesting, scientifically superb assets in there if they work, but it's still a fairly risky pipeline. And I'd like to bring in some assets, and Priya's interested and Adam's interested in doing this too, building that pipeline out for longer-term sustainable growth.

Christopher Schott Analyst

Okay. That's great. Maybe pivoting over to LEQEMBI, just an update in terms of the launch and progress you've made addressing some of the barriers to uptake.

Christopher Viehbacher Executive

You know, one of the things that we have to remember with LEQEMBI is that we are dealing with pioneering and breakthrough almost every day. Remember, until about a year ago, there was still an awful lot of questions about, did it add value to remove amyloid plaque, and the Clarity study clearly demonstrated that. Not only in terms of CDR-Sum of Boxes, but in terms of activities of daily life. But of course, up until now, there hasn't really been any disease-modifying treatments for Alzheimer's patients. And most of them are actually being seen by primary care physicians.

So now there's kind of a rush. We've got to get appointments with the neurologists, not everybody who has Alzheimer's is eligible for treatment. They have to be cognitively assessed as to whether they have MCI or early dementia. This is changing an awful lot of how neurologists practice medicine. There's a lot of teamwork that's needed.

We need the PET scans, the MRI to monitor. One of the things that we're looking at, though, are reimbursement has not been an issue. CMS came out not only on reimbursement of LEQEMBI but also on the PET scans. And some of the things that are quite interesting, because of the lengthy sales cycle, it can be 2 to 3 months between the time someone says, "I want to go see a neurologist," before they actually get drug in arm. And so what we try to do is look upstream and see what kind of indicators we have for progress.

So numbers of PET scans are going up. When we talk to people who are providing the PET scans, they're seeing lots of activity. People who are providing the blood-based biomarkers and diagnostics are seeing increased activity. We're seeing a significant increase in the numbers of new patient starts on the registry. And in terms of reimbursement, CMS said, okay, we're now changing and clarifying the reimbursement for PET scans, but that has to be pulled through by the dozen or so MACs that are out there.

And they typically don't move that quickly, but they have moved faster than anybody has ever seen before. A lot of the IDNs were on formulary, and they have done out-of-cycle P&T

committee meetings because they see it as an urgency. We certainly have patients waiting for treatment. So the real job is just establishing the care pathways, getting the policies in place and the blocking and tackling of being able to process the patients. So I think we're feeling pretty good.

I'm looking forward to seeing how the January sales play out. A lot of positive data in December, but December is kind of a funny month with the holiday schedule. But I think we're certainly seeing an awful of tremendous progress on LEQEMBI.

Christopher Schott Analyst

So in terms of the -- I guess, the ramp from here, is it really just kind of getting the neurologists kind of getting their treatment paradigms down? Is that -- and education? Is that the biggest gating factor at this point, in your view?

Christopher Viehbacher Executive

There's going to be a number of things that we have to pioneer, again, because nobody has been treating patients, essentially. So one of them is, I think that the primary care physicians will play a role at some point because patients coming in, if it's hard to find an appointment for a neurologist, one of the best things would be is, can we do a triage of those patients before they get to the neurologist? And this is where the blood-based diagnostics will play a big role. The next thing is a lot of physicians saying, well, okay, there's -- we can't obviously expand the number of neurologists quickly. But not everything has to be done by the neurologists.

And so some of them are hiring nurse practitioners to do some of the work. We're not seeing any capacity constraints on PET scans, nor on MRIs, nor on infusion centers for the moment. So I think that will flex. So largely, it is really around the care pathways and just establishing those. And that increases every day, when -- the number of centers ordering from -- when we did Q3 earnings to now was up 37%, for example.

Christopher Schott Analyst

An excellent point. Are you seeing in terms of where the prescriptions are coming from? Is this mostly still being driven by kind of top KOLs? Or are you starting to see that broaden out a lot more into the community?

Christopher Viehbacher Executive

Actually, it's starting to broaden out. There's still -- we've probably got about a target of 10,000, and we're working our way through that.

Christopher Schott Analyst

And then in terms of your team's efforts, how much time are you spending on I guess, the broader population versus kind of walking in those core prescribers?

Christopher Viehbacher Executive

We're still focused on some of the top centers, largely because we wanted to get the -- really the go-to-market model down. We have these -- we call them neurology account specialists,

NASs. And that's quite a heavy lift for a specialist, because they've got to go in and explain the care pathway with the office. We have to do a lot of education around ARIA. We have to go through and explain not just the reimbursement for LEQEMBI, but the reimbursement for the physician's time, for the scans and everything else.

And then, by the way, why LEQEMBI, which is the selling proposition? So it's quite a heavy detail, if you like, and visit with physicians. And we really wanted to get that model, and there's other people who are just looking after the patient journey. There's people who are looking at regional KOLs. And so we wanted to get that down and get a certain critical mass.

And as sites become ready, then you can start to ramp up your promotional effort further.

Christopher Schott Analyst

Okay. Just like tie this all together, just help me bridge a little bit from where we were with 3Q results in terms of number of patients who are on drug versus the 10,000 patient target by April '24. I guess my question is just how confident are you in that number? Is that a number that makes sense to reset, at some point?

Christopher Viehbacher Executive

Well, remember, the 10,000 was really designed to try to give people some sort of milestone because there are no real analogs for this launch. I haven't found a decent analog anywhere. So what I think we were trying to say is this isn't going to be 100,000 patients, but it's not going to be 1,000 either. So that is a trajectory. And I think where we are right now, there's nothing that we're going to do that's going to change just on the trajectory.

We'll get there, we don't get there. I think everything we're seeing, there's no reason to say that we can't get there. But again, the data were kind of choppy in December, so for me, I'm really looking for the January data. But where we are right now is the 10,000 isn't really what we're interested anymore. It's how do we now get to the 100,000?

And so that's where we're focused. But you can't get to the 100,000 unless you really got this go-to-market strategy really nailed down. And I think we're increasingly confident in that model.

Christopher Schott Analyst

So your focus is more making sure you getting the underlying pieces in place, and the numbers, the number of [indiscernible]. The other question I have was just duration of therapy. I know you've talked about the importance of continuous dosing. Some of the feedback we get from physicians is a bit bifurcated of some wanting to basically dose to plaque clearance, others looking at longer term. How are you thinking about how that plays out?

Christopher Viehbacher Executive

Well, remember, we're probably going to be always well ahead of where physicians are because right now, the physicians are interested what's in the label and what do we have approved. And of course, that's all we can go out and tell. But as we think strategically about

where this product is going, we're looking at other data. So right now, you're right, the Clarity study showed, okay, you remove the plaque, and you've demonstrated a cognitive benefit. But the first question is, well, what happens when you stop?

And we showed at CTAD last October, that actually, in a 24-month extension study, that actually there is a benefit to continuing on therapy. So we will be -- we intend to file for a maintenance indication by the end of the first quarter of this year. But the other was -- why did so many drugs fail before LEQEMBI? And there are really 2 reasons. One was, could you get enough drug across the blood-brain barrier?

And the second one was, were you in the right patient? And we all learned, okay, we needed to move earlier. And now we, obviously, with LEQEMBI, are getting into the brain with the quantities we need. But have we still found the right patient? And one of the -- some of the data we showed was a substudy of Clarity, where we looked at really low tau patients, so really early patients.

Those data are really striking because now you're seeing something like 75%, 76% of patients completely stable for 6 months on the first 6 months of therapy. And intriguingly, which was really amazing, we actually saw an improvement. And then we said, how can that improve? Neurons are dead or they are not dead. Well, it turns out that maybe that's not the case.

And I think those data are interesting because there is a promise if we can actually show this -- these results in our -- in the AHEAD clinical study that we have ongoing, it's going to make sense that we go even before patients have symptoms. The earlier you go before too many neurons have been damaged or killed, you're going to get a benefit. That's at least the promise that I think we are seeing out of that data. Now we have to prove that with the clinical trial that's ongoing. So you could actually see people on drug for quite a long time.

And is prevention even a possibility? That, you have to think about for the longer term. But the other interesting aspect of those data were why did you see an improvement? And nobody had seen that. And it seems like there are these protofibrils, which are in the soluble element of the amyloid plaque.

And those protofibrils seem to have some impact, that's at least a view of some KOLs, on synaptic function. Now LEQEMBI operates on those -- has an efficacy against those protofibrils that other products don't have. And so again, if we can actually continue to do research and show that we can get into the right patients earlier, we could actually really have a dramatic impact on the course of this disease.

Christopher Schott Analyst

Those earlier-stage data sets are really, really exciting, so we need to watch the preclinical studies pretty closely. The other question I have just on a bigger picture with relationship with your partner here. Can you just talk about how the commercialization roles are setting up today, just the general status of the relationship?

Christopher Viehbacher Executive

So we started with the U.S. This is the first country. And this -- as I described, this go-to-market model is pretty complicated. And for those of us who've been in this industry a long time, and you're working in co-promoting or in co-marketing, these are not easy things to actually execute on. And so we decided in the U.S., let's just have one of the companies go out there and in a Phase I, if you like, really establish the go-to-market model.

And at such time as we decide to increase, then let's talk about what role, for instance, Biogen will play. And that was in the U.S. Now outside the U.S., because I think we've gotten a lot of information around the go-to-market model, I'm actually flying to Japan tomorrow night for the launch of LEQEMBI in Japan. And Biogen is in the front lines of launching LEQEMBI in Japan. And that's our intention to do in Europe as well.

So one of the things that we have tried to do is how do you make this relationship not only work together collaboratively, but how do you make it efficacious and efficient? Because there's an inherent inefficiency when you get 2 companies trying to do things. And what you find is every company wants to do half of everything. That is hugely inefficient. So I think we are both conscious of the fact that we have invested a lot of money in this.

And how do we make this collaboration profitable as well as successful?

Christopher Schott Analyst

Do you -- it sounds like ex U.S., it's a more blended model. But does the U.S. model evolve, do you expect, over time?

Christopher Viehbacher Executive

I do expect that, yes.

Christopher Schott Analyst

That's something this year or that kind of...

Christopher Viehbacher Executive

We'll probably give you an update of that with Q4.

Christopher Schott Analyst

Okay. Okay. We'll watch closely there. Other question just on LEQEMBI's subcu. So just help us put some of the data we saw last year into context in terms of your confidence in that program?

Christopher Viehbacher Executive

Again, here, we got another breakthrough. I mean how do you get an antibody through the tissues and into the brain? And this is the first time that someone has demonstrated that we can do that on a bioequivalent basis. So that's a huge success, and that's going to be extremely important because as we talked about, we're going to be on -- patients will likely go to be on drug longer over time as the clinical trials read out, and we get these other indications approved. And so obviously, the biweekly infusion is not going to be very

convenient.

So the subcu will play a big role. We're obviously in a lot of discussion with the FDA, and there is still an intent to file an approval for subcu at the end of the first quarter of this year.

Christopher Schott Analyst

Okay. So I guess in terms of the data we saw, do you think there'll need to be a dose adjustment? Or do you feel comfortable with the dosing that you...

Christopher Viehbacher Executive

Well, first, we only saw 6-month data, so we now have to get the 12-month data. And so we'll look at that, and we'll have a discussion with the FDA. But I think there is still an awful lot of confidence that we can file a subcu at the end of the first quarter.

Christopher Schott Analyst

Okay. Great. I guess just maybe then putting it into broader context, how important is subcu for LEQEMBI in terms of the uptake?

Christopher Viehbacher Executive

Over time, I think it's going to be hugely important. There are some people who think, well, subcu is really important short term. I'm not as convinced about that because everything we've talked about is really prior to the initiation of treatment, getting through the cognitive assessment, getting the PET scans and everything else. And the subcu versus infusion doesn't really have an impact on that and for the initial period of plaque removal. But I think as we look to maintenance therapy, and if we're looking at going earlier on patients staying on drug, I think the subcu is extremely important for the long-term development of LEQEMBI, for sure.

Christopher Schott Analyst

Maybe just one last one. As I think about broader use of blood-based diagnostics, how important is that going to be of maybe having less need for PET scans in terms of the uptick of these products?

Christopher Viehbacher Executive

I think it's going to be a game changer. Most Alzheimer's patients are at primary care. And Alzheimer's is not simple to diagnose. So is this normal aging? Is this dementia?

Is this Alzheimer's? And it can take quite a while. It can take years before someone actually says, "Well, I think you really need to go see a neurologist." And this is where the first role of these blood-based diagnostics can play a role because you can get a much clearer read on is this Alzheimer's or is this dementia, for example. It can play a role, I think, in triaging the patients so that those who really are eligible are the ones who go to see the neurologist. And over time, what the companies who provide these diagnostics are doing are looking at validating these diagnostics such that you could get a confirmed diagnosis of Alzheimer's in place of a PET scan or a CSF.

That will probably take another 2 to 3 years, but it's quite interesting. Until you actually have a treatment, there is not the same investment in diagnosis, and we see this also in rare diseases. And I think that's what's happened. Now there's a treatment, so now these -- the diagnostics have been around, but nobody was really interested in using them if I didn't have a treatment. So now there's an awful lot of activity.

I mean Quest and Labcorp, CN2 (sic) [C2N], these are all companies that are working a lot to bring these diagnostics to market, and they're actually out there and being used today.

Christopher Schott Analyst

Yes. As we think about over time, those are going to be a key piece of this. Excellent. So maybe just pivoting a little bit to SKYCLARYS. So maybe start with this update on the U.S.

launch and how that's progressing.

Christopher Viehbacher Executive

That -- there's a tremendous launch. I think when we start comparing this to analogs, we are outperforming all the analogs, even our own SPINRAZA. There are a couple of reasons for that. One is, remember, SKYCLARYS was originally approved, but then couldn't come to the market because there was a manufacturing issue. And so it didn't actually get to market until July.

So there was no question that there was some warehousing of patients, and we saw that. But there's also an extremely active patient advocacy group that has been hugely helpful in really raising awareness of the disease and the availability of treatment. We're seeing that same kind of interest actually outside the U.S. And remember, one of the interesting things about rare disease is, we're not so U.S. market dependent.

If you look at SPINRAZA, 2/3 of our sales are actually outside the U.S., and we expect the same to be with SKYCLARYS. So we're in the process of setting up early access programs in a number of European countries. Actually, Latin America is expected to be a big market. There's no market in Asia just because of the genetic makeup of these patients. But it's off to a very strong start, and we're very pleased with the launch.

Christopher Schott Analyst

Great. Maybe just digging a little bit more detail on the European market. Just elaborate a little bit more versus the U.S. in terms of patient identification, patient advocacy. Is there -- are similarities and differences, I guess, I think about how that ramp could go?

Christopher Viehbacher Executive

Well, I mean there's 2 differences, I guess. On the one hand, patient advocacy groups are not quite well developed, but the main group, FARA, for instance, is already establishing itself in Europe, but there are going to be other groups that will be helpful. At the same time, you only have single payer systems. And actually, if you're in the business of vaccines or if you're in the business of rare diseases, those single payer systems are actually quite helpful. I mean one of the things that Alisha deals with in launching in the U.S.

is that you still have to go around all these payers, and then there's issues about getting the refills. You don't really have any of that in Europe. And generally, the pricing is actually quite acceptable in Europe. We certainly saw that with SPINRAZA. So we're using SPINRAZA's analog.

And I think that's why there was so much attention to the European approval. It's not usual that the European approval really matters to most drugs, but on this one, it does. So -- and we've had outreach from 26 countries around the world who are inquiring when is the drug going to be available. So it's -- there's nothing else out there for these patients. The next major thing that we have to do is launch a pediatric study, because a lot of patients are actually diagnosed under the age of 16, and we don't have that in our indication statement today.

Christopher Schott Analyst

Okay. Great. Maybe post-Reata, can you just talk about financing capacity and, you mentioned before, kind of this new desire to derisk the pipeline a little bit more. Kind of where is the BD focus right now? Is it pipeline versus in market or?

Christopher Viehbacher Executive

Well, we couldn't afford to do another Reata, at least this year, but we're generating quite a bit of cash flow every year, and we certainly have the capability of doing licensing deals. And I'm not sure we need to do another Reata. I mean, if we found one, I think we would. But I think we're really going to be focused on earlier-stage licensing. A lot of our pipeline, our ASOs are from Ionis, and they address huge unmet needs.

And again, if they -- if successful, each of them, whether it's in Angelman or sporadic ALS, we have another -- our ASO for tau is the crown jewel in the pipeline. Plus we have 2 molecules for lupus, one with -- partnered with UCB and we have our own litifilimab for SLE and CLE. But there's -- Biogen has always been out there on the risk curve on the development, and we'd like to complement the pipeline with more assets in rare diseases and in certain defined areas of immunology. And part of the reason for that is in most of what we do at Biogen, we can't do a proof-of-concept study. So we're doing these regulatory studies, these approval studies.

Lengthy, expensive and have no idea whether they're going to work or not. And I think what we'd like to do is have parts of our R&D come through a classical drug development chain, where we can do a Phase II and assess safety and efficacy before we spend money on the pivotal studies. And rare diseases, I think, really fits with our commercial capabilities as well as our scientific capabilities. And Biogen has always been an immunology company. I mean, we've been in MS from sort of the get go.

So I think we can expand our pipeline range without having to acquire an awful lot of new capability.

Christopher Schott Analyst

You think about being tuck-in kind of centered around those areas.

Christopher Viehbacher Executive

In research, we've hired a new head of research with Dr. Jane Grogan, and there, again, I think we can do so much more. If you're Biogen, we're in one of the most prolific R&D centers in the world, and we've done some collaborations, but I think we're going to be looking to increase the amount of collaborations that we're doing in the Boston-Cambridge area, but I think Jane has come from the West Coast, and I'd like to make sure that Biogen is as present in the West Coast as it is on the East Coast.

Christopher Schott Analyst

Great. Maybe just shifting to the kind of P&L and base business. Maybe to start with, just thinking about 2024, kind of pushes and pulls we should keep in mind for the portfolio?

Christopher Viehbacher Executive

Well, I think, a couple of things. One is, remember, we did a transaction for $7.5 billion. If we had done it 2 years ago or 3 years ago, money was -- didn't cost anything. And so obviously, we had a lot of interest income on the money we had in the bank that we're not going to have this year. So remember that when you get below operating income, that there's not as much interest income as we did last year.

But equally, there are a number of positives. First is that we're shifting that revenue mix, so getting a lot more product revenue and less contract manufacturing revenue, which has a positive accretive benefit on gross margin. Second thing is we have a huge facility in Switzerland in Solothurn for the manufacture of LEQEMBI, so we had an awful lot of idle capacity costs last year that we're not going to have this year. And then you have SKYCLARYS, which is a small molecule and has a high gross margin. So I would say we're going to have a better gross margin this year.

And you're going to see some of the flow-through of Fit for Growth flowing through on our OpEx line. So we're certainly -- we targeted 2025 to have OpEx-to-revenue ratios equal to our peers.

Christopher Schott Analyst

Okay. Okay. Great. And when I think about kind of Biogen's trough year into -- whether it's revenue or EPS, when should we kind of think about that trough hitting and the company kind of heading to growth?

Christopher Viehbacher Executive

We'll give you an update on that Q4.

Christopher Schott Analyst

Okay. Stay tuned, it sounds like there.

Christopher Viehbacher Executive

I think we have all of the elements to grow now. So -- but I don't want to put out a press

release today.

Christopher Schott Analyst

That sounds good. Maybe just one last one, just touching on the margins again. With the new accounting for LEQEMBI, I think you mentioned by 2025 those margins normalizing. Just what's a reasonable margin to think about for your business, looking out 4 to 6 years as we think about SKYCLARYS ramping, LEQEMBI becoming a bigger contributor. Like what does that look like?

Christopher Viehbacher Executive

I think you want SG&A roughly around 20%, 21%, 22%. It all depends on where you are in launch cycles. Obviously, companies that are launching have a little bit lower ratio, some would mature. But I think if we're, over time, around the 20% and R&D around 20%, so you got kind of a total OpEx to revenue ratio of 40%. The one thing I would say in a company like Biogen, in my days at Sanofi, we always were focused on this 15%.

I think Biogen has a much higher scientific level than most companies. I wouldn't want to constrain our R&D budget if we actually find projects. I think we've established a lot of discipline and that if we're going to invest, there's going to -- we think that we've got a real discipline to make sure that only things that make sense are going forward. So that could increase, but then we would have to demonstrate that there's value creation there. But I wouldn't want to cap us on that.

But otherwise, I think if we can get to that, then we'll have a bottom line that is comparable to our peers.

Christopher Schott Analyst

Yes. That's helpful. A couple of other quick ones. Biosimilar business, just update on that process of where you are and how that fits in the portfolio?

Christopher Viehbacher Executive

Yes, we'll have another update on that in Q4. That -- it's a bit of a complicated business because we sold the equity in the joint venture last year at a very good price. And we have all the distribution rights for Samsung in Europe, and we have our own proprietary biosimilars that we're launching in the U.S. And so we're in discussion with a number of parties about that, but it is -- it's kind of a complicated business to deal with. But we don't -- I think it's not necessarily core to Biogen.

Christopher Schott Analyst

So the goal is to -- there's maybe a better owner for that business than Biogen. The other one, just on ADUHELM, just update in terms of Biogen's decision with where you go with that product?

Christopher Viehbacher Executive

Yes. I'd like to say that's kind of one of the hardest business problems I've almost ever

confronted. You've got a product that clearly works, but the studies to finish the confirmatory studies is pretty significant. And the question is, by the time you get there, what's the market going to look like? And so we are actually in discussion with outside parties and outside financial interest, and we're coming to the conclusion of that, and we'll give you an update of that at the Q4 earnings, too.

Christopher Schott Analyst

Okay. Great. A couple of other ones. R&D pipeline. I think you've mentioned a couple of before, but I guess what do you see as the major opportunities in the pipeline?

And what should we be paying most attention to?

Christopher Viehbacher Executive

Well, one is litifilimab, which is actually a homegrown asset. Lupus is a huge opportunity, but it's been a very complex target. I was at GSK when we developed BENLYSTA, so I know this disease pretty well. What is -- what I particularly like, it has a cutaneous lupus. And part of the problem of lupus is you've got numerous organs involved.

And I think on the skin side that we might have a little bit more success. Certainly, we are getting inbound interest on that product, so that tells me that we're not just believing in our own optimism here. I think the ASO for tau is extremely important. What really started the whole ADUHELM-LEQEMBI progression was a study that Biogen did 10 years ago called PRIME. And it was in that Phase I study where we actually were able to demonstrate, for the first time, a benefit on cognition.

And I think, if anything, we've seen even more promising data. It's all very early, and we're in a Phase II that is ongoing. But if you look at tau, tau determines the severity of Alzheimer, and we've been able to demonstrate that we can knock down tau. Antibodies have not, because it seems like you have to act intracellularly. So the ASO is very good for that.

And I think that could be another major market in Alzheimer's, the complementarity between reducing amyloid plaque and reducing tau makes an awful lot of sense over time. So I think that one is one to watch, but we'll have data in the first half on our ASO for Angelman's. We'll have some data on the sporadic ALS for ASO as well. So we've got a number of things that -- and we have also completed another study in lupus. We have a product in collaboration with UCB.

Phase III has completed enrollment, and we'll have data on that Phase III in about the midyear.

Christopher Schott Analyst

On the tau program, what's the next update we should kind of think about for that one?

Christopher Viehbacher Executive

Probably looking at an interim analysis, but it's probably another year or 2 away. 2 years away, Priya?

Christopher Schott Analyst

Yes.

Christopher Viehbacher Executive

2 years.

Christopher Schott Analyst

There's the last topic here, just on...

Christopher Viehbacher Executive

It's always good to put your head of R&D under a little pressure in these meetings.

Christopher Schott Analyst

Get the [yes] now in. On ZURZUVAE, can you just talk a little bit about just, as you mentioned before, how the launch is going and just expectations for the first year for that one?

Christopher Viehbacher Executive

The interesting is expectations are quite low. But when you look at it, the unmet need is phenomenal. Only a fraction of women are being treated for this, and it's devastating. And what was amazing is when ZURZUVAE got approved, we had this unprecedented media wave. I mean, it's been in TIME Magazine, on CBS, something like 5 billion media impressions.

And I think what I'm hearing from our U.S. team is essentially we're at the crossroads of 2 major societal trends on women's health and mental health. And so actually, there's a huge amount of resonance that we need to help women with this condition, help to displace some of the taboos around this and actually provide a treatment that can act quickly. This onset within 3 days could be quite important for women who are trying to cope with new children and feeling guilty about this. So we've come up with a commercial plan, which I think recognizes that we have to build this market, and we can do this profitably.

But I actually think -- I would actually think that ZURZUVAE is probably an underestimated opportunity. I think there's upside here.

Christopher Schott Analyst

And you think a PPD-only indication is -- can be a profitable business for Biogen?

Christopher Viehbacher Executive

I think it can be, yes.

Christopher Schott Analyst

Okay. Excellent. Maybe just to wrap up here in the last minute or 2. Just as I -- you walked through some of the pipeline, but if you look at catalysts for 2024, what are you most focused on or kind of updates that we should be watching most closely?

Christopher Viehbacher Executive

Well, clearly, LEQEMBI. Although LEQEMBI, obviously is not profitable this year, but it is a major growth opportunity. SKYCLARYS will really be driving an awful lot of operating revenue as well as top line revenue. And obviously, the cost savings on Fit for Growth. And I think people could be surprised potentially by the gross margin.

I think we're going to do better. So we'll be giving an update on guidance for the year at Q4, but like I said, I think we are in a much better place than we were a year ago. But we equally recognize we now have to pull this through and execute.

Christopher Schott Analyst

Thanks again for the discussion today. You made a lot of progress in the first year as CEO.

Christopher Viehbacher Executive

Thanks, Chris.

Christopher Schott Analyst

Thanks again for joining us.