Biogen Inc.

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Terence Flynn Analyst

Well, thanks for joining us, everybody. I'm Terence Flynn, the U.S. biopharma analyst here at Morgan Stanley. We're very pleased to have Biogen. Joining us today from the company is Chris Viehbacher, CEO.

Chris, thanks so much for being here.

Before we get started, for important disclosures, please see the Morgan Stanley research disclosure website at www.morganstanley.com/researchdisclosures. Well, thanks so much, Chris. I really appreciate the time today. I know it's a busy time at Biogen.

Terence Flynn Analyst

Maybe to start, I thought we could talk about what's some of your key priorities are over the next year?

Christopher Viehbacher Executive

Yes. Thanks, Terence. It has been a busy, I think it's 8 months, maybe 9 months now. I think I certainly learned when I was at Sanofi, you want to get change done early in your tenure because it actually takes time to pull through. And that's kind of when the organizations are most open to change.

We started off with people, products and pipelines and that merged into 5 priorities. And I think we've made really good progress on all 5. One was really reorienting the company when I got there, everybody was still really focused on the MS franchise and that we had LEQEMBI.

We were hoping to launch zuranolone. And so that meant a shift in not only focus but also the development of new capabilities.

We had a cost base that everybody in the industry were saying was way too high and we had to address that. We have had 5 heads of R&D in 10 years and so that has led to a big mishmash in the R&D pipeline and we needed to sort that out. We do have a couple of existing products that have patent cover into the mid-19 -- 2030s, which is VUMERITY and SPINRAZA. So looking to certainly stabilize and get growing SPINRAZA again and really taking advantage of VUMERITY, which is really now the only branded product in the oral space.

And then finally, looking at derisking our growth path through external development. And of course, we announced the acquisition of Reata. So I actually think now we've got all the elements to really grow Biogen sustainably. Certainly, as we look over the next 3 years, I think we can aspire to substantial growth. Of course, I learned early on in my career, strategy is 10%, execution is 90%.

And so that's what we're really focused on now.

Terence Flynn Analyst

Okay. Makes sense. What, as you look out 3 years, again, obviously, the sustainable growth is an important piece of it but what else do you hope to see? Or where do you think the company will be positioned over that time period after some of this change plays out?

Christopher Viehbacher Executive

Yes. I think one of the things I think we've been trying to do is let's get the company -- because we've had this melting iceberg, let's get the company back on a growth trajectory. And so I think we've got all the elements certainly with the cost reductions, Reata, LEQEMBI, even to a degree, PPD for zuranolone. Where I'm going to start spending a whole lot more time is with Priya and our newly announced CSO, Jane Grogan, really thinking about the pipeline. Because I think, what I'd really like to see happen is that we are growing strongly into the next decade.

And I think there are some very good assets. Priya has done an amazing job of really weeding out some of the nonvalue-added projects and putting our resources behind things that we really like. BIIB080, which is our ASO for tau, for example, I think we'll see some very encouraging new data at CTAD on that.

We've got a couple of products in lupus. One Phase III, we'll see data in the middle of next year. We have another one for cutaneous lupus. There's a product for generalized or sporadic ALS, another ASO and another ASO for Angelman's. So I think there are already some assets in there, with Adam Keeney, our new Head of Corporate Development, I think we're going to be looking at doing more business development.

And then Biogen's research has not been the most productive. In 45 years, actually, litifilimab for cutaneous lupus and ADUHELM were really the only 2 products to make it into development of any significance.

Jane comes as an immunologist and I specifically wasn't looking for a neuroscientist and so that's an opportunity also to start reshaping the company over a longer period of time. So I'd certainly going to be looking to see how do we really transform Biogen into a scientific and research powerhouse as well as a commercial one.

Terence Flynn Analyst

And is that -- is it fair to think that immunology is going to be a key part of that diversification? Obviously, you have a extensive legacy in neuro, again, CNS. But as you think about this diversification pivot, is it fair to think immunology is going to be a big part of the story on the forward?

Christopher Viehbacher Executive

Yes. I read one analyst report over the weekend that I thought actually was something I certainly would agree with. I think we got into neuro through immunology basically with MS. I mean, MS is really an autoimmune disease and we're in things like lupus and ALS. So I think it's a natural fit.

Now immunology is quite big. And of course, inflammation is popping up everywhere as a problem even in the Reata drug actually. So I think we can actually build upon immunology. I don't see us, just because you see Genentech, we're not going to get into oncology. That's for sure.

But I do think the rare diseases, parts of immunology, which is pretty vast area, probably narrow that down to neuroimmunology. Still the neuropsychiatry and obviously, Alzheimer's because with Alzheimer's, we aim to be with our partners a leader in Alzheimer's, and LEQEMBI is only the first step in that journey.

Terence Flynn Analyst

Okay. Great. You also mentioned looking externally, you have the Reata acquisition. But how do you think about business development from here? Is this -- does this kind of put a pause on activity given the size of that and integration and you have a launch to think about?

Or is this something you can parallel process and we should still expect some normal course of business development here?

Christopher Viehbacher Executive

I think my CFO will say that I probably spent the budget on acquisitions for a while. So I think we will shift a lot more to probably more early-stage business development, Phase I, Phase II. I also want to transform our research organization into a more collaborative organization. It is to a degree but we aren't the most prolific biotech communities in the world. And I think we can do an awful lot more with equity investments and collaborations in an early stage in research.

So I think Adam is going to be pretty busy with that.

Terence Flynn Analyst

Okay. Maybe the other piece you talked on is just the Fit for Growth strategy here and rebasing the cost structure of Biogen more along the peer group. I think one of the pushbacks I hear from clients is just, how can you guys do that and also invest in both the LEQEMBI launch and the Reata launch and still come out with a good commercial outcome, I guess. So how do you think about that side of the coin is not just taking the cost down but the investments required to really make these launches a success.

Christopher Viehbacher Executive

I think -- I keep telling my team, one of the most underestimated words in any book on leadership you'll ever read is the word and. It's being able to do "and" is really what separates people from being really terrific or not. You have to manage the short term and the long term. You have to manage innovation and you have to be cost effective. You have to manage your cost and you have to launch successfully.

And there's an awful lot to how you do that. We have actually had surprisingly some investors say, are we cutting too much. And I would assure everybody that, that is certainly not the case. Less than, I think, 10% of the head count that will depart is actually customer facing. The reality is, is that when you have companies that have an awful lot of money and money was certainly very present when we had TECFIDERA.

We had $5 billion of profit more in 2019 than what we have today. And when you have a lot of money, you get into an awful lot of activities and a lot of layers of management. We have an average span of control of 3. So part of this is reducing cost to be more in line -- all we've done is benchmarked with our peer group. We're not looking to be best-in-class in cost cutting but we do have to be competitive.

But there's also a question of agility. If you have a span of control of 3, someone has to ask their boss who has to ask their boss. When I talk to biotech companies who want to do business development with us, they say, "Boy, Biogen loves to do an awful lot of meetings." And if you have a lot of people, you have to do an awful lot of meetings. And part of it is because nobody can make a decision. And so this is about empowerment, it's about agility.

It's also about retooling some of our capabilities because we have been in really essentially a multiple sclerosis company for 45 years. So this is really an opportunity to reengineer and transform the company and it also has a transformative effect on our bottom line.

Terence Flynn Analyst

Okay. Great. Appreciate it. The other topic that I think comes up, more recently just the Eisai relationship. And so maybe give us an update on kind of where that stands?

And as you think about the forward progress of that relationship, again, you guys have other assets coming up through the pipeline. So like, where do those fit in the broader scope of strategic direction of the Eisai collaboration?

Christopher Viehbacher Executive

It's quite an interesting relationship. The companies has been working together for 8, 9 years now. And when you think about the scale of the investment that these 2 companies

undertook in developing these Alzheimer's antibodies, you're thinking about -- we literally spent billions on just the clinical trial development costs between ADUHELM and LEQEMBI, plus spent another couple of billion on a factory to make it. And so these were big bets for companies that are certainly nowhere near the size of Pfizer. And so when you're making those big bets, there has to be an awful lot of trust in each other.

Obviously, the ADUHELM situation was pretty unfortunate to say the least. And I think that strained relationships. But I would say, today that relationship is thriving again. I've known the CEO of Eisai for many, many years. And that's an important relationship because of the way Eisai also operates.

We have our governance teams but we talk regularly, multiple times a month. And what is important though is, this launch of LEQEMBI is pretty much unlike any other launch I have seen. I have talked about the fact that this is only the second time in my career that I've actually seen the creation of a whole new category. And the relevance of that is pretty important because most times you launch a drug, you've got patients in a doctor's office who are being treated with something, it may not be very good but they're there. Here, we're talking about now neurologists who are already busy doing a lot of other things.

And suddenly now we've got a wave of patients who are wanting to come in. And think about what that means in the doctor's office, you've got to now first do an assessment of this patient to see whether they've got MCI or mild dementia. And have to make sure that the mild dementia is actually caused by Alzheimer's and not something else. So you're talking at least 1 hour of time in the physician's office, probably several weeks to get an appointment to see one. Then the physicians are going to send and they are going to send them to a PET scan.

Well, what about the reimbursement of the PET scan? It is reimbursed but there's still some confusion out there in the marketplace or if they're go to have a lumbar puncture. Now you've got to explain to the patient about the lumbar puncture, which, as we all know, is not a picnic. Then we got to find the infusion centers and I've got to monitor the patients with MRI. So this is a logistically a major exercise.

And we're seeing variability out there. You've got centers like Duke that have been way ahead of the game compared to everybody else and are really moving forward on that. Other centers are catching up. Individual practices, this is something that they're all working through. So there is an element of we need the infrastructure to grow but we need all of these processes to actually take place.

There certainly seems to be demand there. I don't -- I think we're confident in the demand. I think we're confident in the fact that physicians actually want to treat these patients. The CMS has moved quickly actually. And that in some ways, it shouldn't have been but kind of caught everybody off guard because now we can go.

There's no limitation. I mean the registry seems to be pretty easy to operate. So this is now a question of filling the pipeline and pulling the patients through. And ultimately, we will see that. And ultimately, all of these physician practices will get good at this and understand this.

But it is a heavy lift at the start. And I think we'll start to see that as we get through towards the end of the year. I think nothing that we're seeing says that the Eisai guidance can't be met,

which is 10,000 patients by the end of their fiscal year, which is the end of March.

Terence Flynn Analyst

Okay. What -- I mean as you think about the lift requirements, I mean, how -- maybe any metrics in terms of progress that you can provide us with? If you think about like, number of centers that are up and running. I mean, we talked about vertically integrated centers, a community practice, not like Duke but there, it's pretty easy, like they have everything in-house. It sounded like it takes about 3 weeks to get a patient on therapy or infused.

There they can do all the scans but you just talk through all the logistics. And if you don't have everything in-house, you've got to coordinate across all these. So how long do you think that process will take for the majority of your centers before you can see the majority of those centers have a protocol in place so that they're up and running and it's a 3-week process or something to get a patient on drug?

Christopher Viehbacher Executive

Well, I mean the key metric really is the site activation and the site readiness. And we've gone out to see 700 centers today going through the P&T committees. So they're getting the reimbursement and weighing through all of that. I think the field force is just really busy on all of the logistics and getting that through. So I think it gets more and more.

And that's why I think in some ways, having the target of 10,000 at the end of the first quarter is more of a relevant benchmark because we know it's going to be choppy up before that and there'll be some centers that are off to the races and some that will take longer and it's kind of hard to predict, to be honest, how fast it's going to go.

Terence Flynn Analyst

Okay. Understood. And one other question we get is just -- obviously, you have the JV across both companies. How much visibility on a weekly basis do you have in terms of all these key metrics? Like are you getting the data real-time like Eisai is?

Or are you guys getting it on a lag? Again, I think investors are trying to understand like how much data are you getting and at what frequency, from a launch perspective?

Christopher Viehbacher Executive

I think the collaboration has been great going with the company and we've actually worked with Eisai, really leveraging the experience of ADUHELM. Although ADUHELM never really got out there in the marketplace, Biogen actually has all this expertise of how do you assess the site? What are the key metrics that we need to look at? We actually used a consulting firm to go back and actually capture the learnings and we have shared those with Eisai. So we've been working with them on the development of the key metrics that we want to watch and share.

It is still very much news from the field that really is driving this. But as I say, we don't really see anything on the demand side here. It is really the logistics question.

Terence Flynn Analyst

Okay. Got it. I guess the other relevant question we're getting is just around the subcu formulation, obviously. I guess I had underappreciated the once-monthly dosing versus every other week dosing that [indiscernible] has, as being maybe somewhat of an advantage. You guys have the advantage of maybe less ARIA with LEQEMBI.

And so a physician survey we did, suggested about equal market share over a couple of years. And so I guess maybe, what's the importance of subcu? And are you confident in terms of the path to market for the subcu formulation?

Christopher Viehbacher Executive

Yes. I think you have to step back and say what's the treatment of -- how is the treatment of AD really going to evolve, right? So remember, until we really had the Clarity study, we hadn't really had the definitive evidence that actually reducing plaques had a benefit on cognition, right? So everybody is looking at kind of this 18-month period and we reduced the plaques and we only studied in patients where we actually had symptoms. So we started with what we thought were early-stage patients with MCI or early dementia.

But -- then the natural fact, those aren't early patients at all. And then now the immediate question is, well, we removed the plaques, what happens then? The plaques come back. And so I think we're going to see a complete change in the treatment paradigm over years, where, on the one hand, you're going to see a maintenance market, you're going to have a plaque clearing market. And we have this AHEAD study that's going on.

What you really want to do, is actually get people before they're symptomatic. There are probably people sitting in this room who have plaques forming in their brains and they don't know it, right? And that's where also the development of a blood diagnostics will help. There are some neurologists who are saying that we'll probably have p-tau in the normal blood bank [indiscernible] that we all do when we go in for our annual checkup. So when you put that in that context, the subcu becomes quite important, right?

Because I think it's less important if you're looking at that plaque clearance stage. But if you're going to be on this drug potentially for multiple years, then the subcu is clearly an awful lot more convenient. So the intent is to have a filing by the end of Q1 of next year and doing all the work for that. And I do think, though, you're going to see different patients at different stages. And I think there's -- first of all, there's more than enough market for 2 drugs and exactly how they work and where they're used is going to evolve.

Remember, right now, donanemab has a very limited space of time in which it can work. So that whole spectrum that we just talked about, donanemab isn't really going to play. Now Lilly, of course, isn't sitting still. They're thinking about that, too and they have other antibodies that are coming along.

Terence Flynn Analyst

Okay. Makes sense. Again, you mentioned blood-based diagnostic. Obviously, really important when you think about the longer term, even diagnosing earlier in the treatment

paradigm. So what's the best guess in terms of when something could be available on that front?

Christopher Viehbacher Executive

Blood diagnostics? Well, I mean, they are available now but they haven't really been validated. In an ideal world, we'll get them validated to a point where we could replace the PET scan and the lumbar puncture, right, because that would have both a patient convenience but also a cost benefit for the whole system because in addition to the drug, you've actually got quite a lot of ancillary care. And that would also give you the confidence to actually diagnose someone presymptomatic. Now we are using the CN2 diagnostic actually in the AHEAD study to help find patients but of course, that's still being validated with PET scans.

Terence Flynn Analyst

So would sort of that be the first validated data set that we should think about, I guess?

Christopher Viehbacher Executive

Yes. I think they are -- all of the diagnostic companies are now working. I mean the diagnostics has been around but until you actually had a treatment, there was no commercial market for the diagnostic. Now there is and I can tell you Quest and LabCorp and a bunch of other companies are all scrambling to get the data for these diagnostics. But realistically, it's probably still a couple of years before we see it fully used.

Terence Flynn Analyst

And one more on the imaging side, is the -- on the PET scan reimbursement. So I know that NCD was revoked. And so now it's at the local MAC level and I know each -- I forgot, I think there's 14 MACs around the U.S. that each has to kind of make an individual decision. Is that process fairly far along so that PET is not a kind of gating item anymore on the reimbursement side?

Christopher Viehbacher Executive

That's where there's still a little bit of a confusion. I mean our understanding is certainly 1 PET scan in the lifetime is reimbursed and because it's also required under the terms of the LEQEMBI reimbursement, separately PET scans are controlled by their own. And that's where there is this change that is in progress, but that hasn't completely played out. And so The MACs don't have that ability today to do that, as I understand.

Terence Flynn Analyst

Okay. Maybe just the last one on the Alzheimer's space. You talked about tau as another target. You're going to have some data at CTAD. I'm assuming that's part of the strategy to stay at the forefront of Alzheimer's care, maybe talk about where that fits into the strategy.

And then anything else behind the scenes that you guys are doing to make sure that you and Eisai continue to be at the forefront here?

Christopher Viehbacher Executive

Well, again, basically LEQEMBI is the first breach in this wall, right? I mean we've all been throwing stuff at this wall, trying to find out how do we make a difference in Alzheimer's without success. I mean tens of billions of dollars of research and development went into trying to find something. And this is the first time where we actually saw something that actually had an impact on cognition. But we all know that we'd like something that does even more.

And so the question is, can we do more with more effective antibodies but we're already getting pretty significant reduction of plaque. So then you start looking at other mechanisms, tau is clearly a major factor in the severity of the disease as we know. A lot of experts are out there are more excited even about tau than they are about Abeta. So that's a logical one. Tau is the one acts intracellularly.

So you need a drug that can go after this intracellularly, that's why we think our ASO is very promising. But we're also looking earlier. We know that microglia and inflammation play a role. So we have a program in TREM2, for example. We are working with some of the diagnostic companies, also even for tau and developing biomarkers.

So certainly, the goal of both Eisai and Biogen is that we will maintain leadership in Alzheimer's. I mean there's -- I mean it's bumpy today. But this is going to be a very significant market over time. And we need to make sure that there are other treatment options available to patients. Do you combine a tau and an Abeta at some point, we want to make sure, first of all, we can demonstrate the benefit of that BIIB080 on its own.

But then a logical question is, does it make sense to combine -- most complex diseases, you end up with combination therapy, right?

Terence Flynn Analyst

Yes. Makes sense. Okay. Great. we talked about high-level Reata but maybe just walk us through kind of timing of the deal closure.

And then as we think about the commercial rollout what are you guys doing to ensure commercial success? Obviously, this is another important launch that investor community is going to be focused on as we head into '24.

Christopher Viehbacher Executive

Yes. So Reata, we -- external growth was -- already in our Q1 announced about where our priorities were partly because we knew that both the LEQEMBI and zuranolone are nonconventional launches. And we just felt that we needed something else that could help us with a return to growth. Also, it's certainly been my view coming into the company. neurological diseases are extremely important, have high unmet need but they are very risky and very high cost.

And while we don't want to abandon that, we were looking to try to diversify a little bit away from that to reduce the risk of what we do, to be able to do Phase II studies that actually give you some indication of whether the Phase III is going to work or not. So moving into rare

diseases, doing more in neuropsychiatry, going back to our roots a little bit in immunology. And so that was sort of a goal and so Reata really helps in that in building out the [indiscernible]. This fits perfectly with SPINRAZA. We have something like an 80% overlap for our reps to operate.

And actually, it provides potentially higher sales growth in the early years and of course, it's going to be, I think, quite profitable, given that you don't have to spend as much as certainly we do with MDD. So I think it's going to be transformational financially over the coming years for the company. People always get concerned about how you pay for things. But I was talking to one investor and she was surprised that I said, well, for me, the IRR has got to be bigger than our WACC. And that's, of course, I don't normally hear that in the biopharmaceutical world.

But this actually is a transaction that also makes financial sense. So in terms of that, we're expecting to close in the fourth quarter. We actually have -- the Hart-Scott Rodino day is today. So we'll find out, I guess, today whether we get a second request or not. And if we don't, we should be able to close fairly soon.

We want to do 2 things with the integration. One is obviously not disrupt the launch. And so I think we will have a smooth transition under Alisha's team in the U.S., they have about 27 reps. We'll bring all the 27 reps in and make sure -- because one of the things I don't want to do is also disrupt the success we've had with SPINRAZA. And sales reps always go for the shiny new toy.

And so I want to make sure that I don't create any kind of distraction from SPINRAZA. And then obviously, we're focused on the European launch. This is a product that's going to be like Biogen. This isn't one where 60% of the sales are in the U.S. This is actually one where the international aspect is important.

We've had 26 countries request drugs from us. And so there's a real interest all over the world. Latin America actually could be quite a significant market for us as well. And there's believed to be, I think, Reata's share, they believe there's 4,000 patients in the Latin America alone. And then actually, I think there's an interesting thing in the pipeline there.

I mean, first, if you look at this Nrf2, which is the driving mechanism for SKYCLARYS, that was also the mechanism, quite a different mechanism for TECFIDERA. And Biogen never really explored that further but we have an opportunity to go back with that and we're looking at can we do things in ALS with this, possibly with Alzheimer's. There's also a product for diabetic neuropathy. I'm quite interested in that because I was involved with initiatives at GSK many years ago. We did a lot of the same experiments.

And the animal experiments actually translate pretty well on efficacy. The problem in this space has been safety. But safety looks good. So if we have that, that could actually be quite a significant opportunity for us as well. So I think we'll keep a small unit in Dallas on the research and development side.

Terence Flynn Analyst

Okay. What -- and just maybe confidence in EU approval -- I know there's been some

discussion among investors on kind of that front and so maybe just speak through next steps on the EU side and confidence and approval?

Christopher Viehbacher Executive

Yes. Obviously, we had access to all of the documentation with the agency under a confidentiality agreement. Obviously, we're still separate companies. And I can only -- I can't say anything publicly that Reata hasn't already shared. Obviously, way we look at it is, the primary analysis was statistically significant.

And then the agency had a question around durability and so we had this 3-year extension study in post hoc analysis but they also stopped the drug, people started the drug again. And you see a nice consistent separation between the placebo group and the treatment group. So I think we believe very strongly in the efficacy of drug. There's no guarantees but I'd say we were able to do due diligence and we're pretty confident. We can't be 100%.

What I can tell you is our financial analysis used a risk-adjusted probability of success on getting approval when we did our IRR analysis.

Terence Flynn Analyst

Okay. Great. And can you get that IRR above WACC without EU?

Christopher Viehbacher Executive

Pretty close, actually.

Terence Flynn Analyst

Okay. Great. Well, I think we're up against time. But thanks so much, Chris. Really appreciate it.

Christopher Viehbacher Executive

Thank you.