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Biogen Inc.

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Terence Flynn Analyst

Great. Good morning, everybody. Thanks for joining us. I'm Terence Flynn, Morgan Stanley's U.S. biopharma analyst.

Very pleased to be hosting Biogen this morning. We have Chris Viehbacher, the company's CEO. Before we get started, for important disclosures, please see the Morgan Stanley research disclosure website at www.morganstanley.com/researchdisclosures. If you have any questions, please reach out to your Morgan Stanley sales representative. Chris, thanks so much for joining us this morning.

Christopher Viehbacher Executive

Great to be [indiscernible]. Thanks.

Terence Flynn Analyst

Absolutely. Maybe I'll turn it over to you to kick off with some prepared remarks, and then we'll go into questions.

Christopher Viehbacher Executive

Well, yes, I'll just say we've been on a journey the last 2.5 years with Biogen. There is a -- it's pretty common in our industry, as you well know, that the more successful you are, the more likely it is you're going to have a problem, right? Because we are in an unstable industry living by the life of our patents. And Biogen's MS portfolio, really great drugs has been slowly declining.

And the relay of growth that we thought was going to be there with LEQEMBI has proven to be slower.

And so that's meant that we really had to reinvent the company to a great degree.

And we've done a number of things. One is we took a major risk in some ways of pulling all the promotion from our MS portfolio. And that actually did not affect the actual sales trajectory. And that gave us a lot of ammunition to go invest in new product launches. We've been doing some business development.

One of the issues of the company had been we were so focused on neurology. And neurology is an exciting area, but it's also a very difficult and risky area.

And we couldn't move too far because of where I think Biogen's capabilities lie, but we have been pushing more into immunology and rare diseases. Building out our pipeline, building out our commercial portfolio. So I'm actually feeling very good about where the company is today. I think we've been through a lot of change, but the culture of the company is intact. We've been hitting our marks on our pipeline so far.

We've got an awful lot of data catalysts coming starting next year.

And so, as I look out, I'd say, unlike a lot of companies, we've kind of got our pipeline more than capable of offsetting our -- the erosion of our existing business. Most of our patent expiries are in the rearview mirror. And I think Biogen is starting to be positioned for a period of long-term sustained growth.

Terence Flynn Analyst

Great. Well, I think we're going to get into a lot of those points. So thanks for framing that. I guess the first one I wanted to do a check on is just the policy dynamic. Obviously, that's been an overhang not just for Biogen, but the whole sector right now with respect to both tariffs and an MFN.

So any update that you can share from kind of your interactions with D.C. policymakers and where we stand in this whole dynamic right now?

Christopher Viehbacher Executive

Yes. This is -- I think every one of us in the industry are spending a whole lot more time on thinking about the dynamics in Washington. I would say, though, from a Biogen perspective, we're a little bit sheltered from some of that, and that's largely because of our product portfolio. So in terms of tariffs, for example, 54% of our revenue is actually outside the U.S. And in the rare disease space where we are predominantly positioned, you can't really take significant price reductions in other countries and make any business because there's just not enough patients.

And actually, that was one of the things I saw years ago when I was at Sanofi when we acquired Genzyme. You can actually get decent pricing in Latin America, in Asia. And that's how we also do 54% of our revenue, by the way, outside the U.S. is that we actually have that. So from an MFN point of view, we're not as exposed either.

So I think where we are, we feel relatively protected from what's going on in the environment. That said, it is a serious point in time for the industry. I mean I remember we thought the sky was falling in when Medicare Part D came in, and we thought the sky was falling in again when the

Affordable Care Act came in. Both of those ended up not being detrimental to our business because there was a volume offset.

The Affordable Care Act expanded Medicaid coverage, for example. And while we pay them awful lot of excise taxes and there were some other things, actually, the business flourished. Here, we're going to see actually a volume decrease, right? Because the number of Medicaid patients is expected to decline after '27, '28. And we're not necessarily seeing any expansion of coverage out of things like MFN or tariffs.

So this is probably a more challenging period certainly than what we've witnessed in the past.

Terence Flynn Analyst

Any sense on -- I mean, this is always difficult. It's one of those crystal ball questions in terms of timelines that you're expecting or when we might know more from a visibility standpoint? Is this like by the next weeks? Is this by year-end? Is it going to linger?

Christopher Viehbacher Executive

I think this month will certainly be wanted to watch. There's -- the government needs to be funded. And so we have to be careful on that. I think under the IRA, I think the next batch of products is going to be announced. The 60-day period of those companies that received the letters, I think, will come this month.

I think one of the things we do see is that MFN is not a simple task, though. And tariffs, yes, but the administration is also extremely concerned around the security of drug supply chains.

And as an industry, we have put hundreds of billions of dollars on the table of new investment in the U.S. So I think there's still enough moving parts here that I think -- and we certainly know that there are a lot of people, for instance in Congress who are very concerned around the competitiveness of the innovative biotechnology industry, particularly seeing the rise in power of China. So I wouldn't say it's all negative. There's a lot of maneuvering that has to happen. But I would say, generally, we're engaged as an industry, and I'm still optimistic that we will be able to preserve our competitiveness.

Terence Flynn Analyst

Great. Maybe just sticking on the strategy front here. You mentioned business development. You guys have been, I'd say, kind of moderately active. Just as you think about the opportunity set, it was interesting, you talked about rare disease in the context of MFN.

But maybe through the evolving policy dynamic, does that change the opportunity set of the types of assets that you guys are looking at now given some of those cross currents we were just talking about?

Christopher Viehbacher Executive

Well, one of the things you certainly start to look at when you look at business development is where is the product made. And there's a lot of places that have gone to China, for example. And so you have to start thinking about, okay, we need to repatriate the manufacturing because the likelihood is that we're not going to completely escape tariffs. There will be some tariff environment somewhere. We don't know what it is or what it looks like.

But one of the things you have to do is, let's say, okay, what's the cost and what's the timeline for bringing something back.

One of the things about business development that is also not clear is what happens when company A owns the rights in the U.S. and company B owns the rights in the rest of the world because in those types of agreements, you typically have antitrust clauses that actually prevent company A from influencing the price of company B. So I think they may -- that is something that I think the industry is thinking about. And again, we haven't seen real clarity on that today. But that could also influence how business development deals get struck.

Terence Flynn Analyst

And that implication there would be that a company would want worldwide rights as opposed to doing some split because you need to control global pricing.

Christopher Viehbacher Executive

Well, the question is, if you have a company that has the -- if you take -- we did ex-U.S. rights with Stoke. So -- and Stoke retained the rights in the U.S. Biogen has those rights ex-U.S. Depending -- Biogen cannot -- and Stoke cannot influence us as to what price we pick in Europe, for example.

But then would Stoke have to pay attention to that from an MFN point of view because it would hardly be fair to hold Stoke accountable for Biogen's pricing in Europe. So you might actually see more of those split rights to avoid the MFN problem.

But that's very difficult to say today. I mean that's things that we are thinking about. And all it really illustrates is that for every rule that comes along, there's going to be an impact somewhere and there may be options for us to try to ameliorate the situation, which again comes back to, this is an industry that has constantly faced an awful lot of challenge. And somehow, I think we've demonstrated resilience in all that. But the uncertainty right now is certainly extremely high.

Terence Flynn Analyst

Yes. You mentioned competition from China, but there's also the kind of opportunity set to do business development deals there. We've seen a number of companies in the sector do that. So as you think about [indiscernible] opportunity versus the competition lens, how do you think about those 2 aspects vis-à-vis your business?

Christopher Viehbacher Executive

I think if we you'll have to do this right. I mean there's clearly going to be caution around data sharing, for example, respect for intellectual property. But if we do get all of that right and everybody plays by the rules, net-net, this could be a positive for the industry because there's greater sources of innovation. At the moment, it seems most of the Chinese companies are not really ready to go global.

And so there are ex-China rights available. Again, you have to do your diligence about the companies and where they did their data. And we've seen it's not so simple to translate. Summit this morning, suddenly, everybody thought, okay, this is a better KEYTRUDA. But when you actually go to replicate the data, it doesn't always work out.

But I think net-net, there could be a bigger source of BD substrate if you add China in there.

Terence Flynn Analyst

Yes. And how should we think about over the next kind of 12 months in terms of your level of activity? Is this something you still see as a priority? Or do you feel like you have enough internally right now and you're kind of executing on these opportunities and then it's more kind of medium term when we should expect more activity from you guys?

Christopher Viehbacher Executive

So BD is still a priority. One of the things I've seen over my years is that really at senior management, we have not spent enough time personally and individually in research. Research is really where you're building a company. And we tend to leave that to a head of R&D. But what we do is we end up spending a lot of money on R&D, and then we have to go do a lot of expensive acquisitions because the R&D didn't develop.

And yet, I think from a capital efficiency point of view, but I would also argue from a capability point of view, bringing innovations at around GLP tox would be the ideal thing. So one of the things I'm focused on is really making sure we have enough of a research pipeline because I see a period of strong growth coming from Biogen. But the time to prepare for patent expiries in 2035 to 2040 is now.

And I take personal -- I'm not a scientist. I know enough to be dangerous. But I'm really focused on do we have enough in research that will carry this company through into the 2040s and 2050s and doing that today. So that's the priority #1. Priority #2 is, I mean, we are balancing the growth of the new products versus the decline of our existing portfolio in MS.

If we could find a business development deal that's pretty close to commercialization, we would do it. Now you look at stock market valuations and you say this should be an M&A paradise. All the valuations are down.

But what you do find is actually good companies are actually getting funded. And it's a good companies you want to buy, and it's not so easy to buy at those levels. And so the good news is that where we are today, I don't feel any desperation to do a deal, but it's always incumbent upon management, I think, to use your capital and see if you can do something that creates shareholder value. But we are very disciplined in how we look at that.

Terence Flynn Analyst

Okay. Great. Maybe we'll move on to the one of the key launch products in LEQEMBI. As you said, it was a bit of a slow start, but there are some inflection points that you guys have talked about. One of those is the subcu, which you recently got approval at the end of August here.

So maybe just as you look out through the back half of this year into '26, how confident are you about the forward trajectory here in the product and it being one of the key growth drivers for the company?

Christopher Viehbacher Executive

So I think Alzheimer's is probably the single biggest opportunity for Biogen still. This was a highly unusual launch, I have to say. And I've been in this business for 35 years. I've seen product launches in just about every therapeutic category there is. This launch was a slow start, but not because of the product and not because of demand.

But this is a dramatic shift in the practice of neurology. And it entailed a huge amount of work for the neurologist. And the neurologist was already a busy practice.

And now you're suddenly putting thousands of Alzheimer's patients where they need a PET scan or a lumbar puncture to get validation of the diagnosis. I need to go now find infusion beds. In some cases, hospitals are requiring the neurology department to a business case about why we should make those infusion beds available to an Alzheimer's patient versus a cancer patient, for example. And -- most neurologists have not had to do business cases before.

Suddenly thinking about adding staff. If you're in an IDN, a lot of those IDNs are pretty stressed financially because of the rise in salaries post-COVID. Some of the hospitals tell us it took 90 days to get approval to hire a nurse who can take care of a lot of this work. So this has been a massive shift in how neurology is practiced. We also have roughly 500,000 newly diagnosed patients every year, and there are 13,000 neurologists.

And so it's taken quite a long time for people to get an appointment.

And the other problem is that you really -- these drugs work best if you can catch people early enough. It's a neurodegenerative disease. Nobody knows how to bring neurons back to life. And so the best time is before too many neurons have died. Right now, that's MCI.

I think by the end of this decade, we're going to see this whole market shift to presymptomatic patients. But today, it's MCI.

And unfortunately, about half of the patients that finally get into see a neurologists are too advanced in their disease to be treated. So a lot of the things that we have been doing are trying to improve the productivity of this neurologist. If you can get one of these precious neurology appointments, how do we get now as many patients through that neurologist as possible. And that means how do we make that easier for the neurologist. One is, can we get rid of the PET scan and the lumbar puncture?

Well, now we've seen the blood-based diagnostic has been approved by the FDA. Now it's not that neurologists are going to abandon PET scans from one day to the next. Neurologists like these scans. It's how they look in the brain, and they've been using them for generations. But I think over time that they will shift more to a blood-based diagnostics instead of PET scans.

The next are the infusion beds. Well, we now have the approval for the subcutaneous formulation. So once the patient has finished the 18-month initiation period, now they can actually take the pen once a week at home. And that eliminates the need for those patients to have infusion beds. We got that approved on a Friday.

And on the Monday, we initiated the rolling submission for the initiation period. And there, now you'll be able to, over time, I think, see physicians switching from, again, infusion beds even during that 18-month period to at-home use of pens.

We still have the MRIs -- and probably in the early days, we may see some patients staying on infusions if they're in an urban setting because neurologists like to have the MRI done when they're coming in from infusions. But I think this will greatly alleviate a lot of the workload at the neurology level. We've initiated a DTC campaign, and I think we're seeing already a strong resonance from that. So all of these confluence of things, we already saw a nice increase. We were above market expectations in Q2 on LEQEMBI.

And I think we're now seeing that this market is opening up, and we're gaining momentum here.

Terence Flynn Analyst

Maybe on the neurologist side, are there any programs that you guys are working on to help increase that number? Or do you think 13,000 is ultimately where we're going to stand and it's more some of the other steps that you've taken? Or is there a way to actually boost that number, so then that also helps alleviate some of this bottleneck?

Christopher Viehbacher Executive

Well, we're facing shortages in a lot of specialties and then particularly post-COVID. I mean we see this actually in postpartum depression as well. We're probably missing thousands of OB/GYNs versus what we need. So I'm not sure that we're going to be able to increase the population anytime soon. But what we can do again is how do we get more patient throughput.

We are looking at doing a PCP pilot because of the blood-based diagnostic, perhaps we can actually get that referral to the neurologist earlier.

Right now, a patient starts to have some memory loss and some signs of dementia. Is that just normal aging? Or is that something else? And it can take 3 or 4 years between the patient starting to complain about some memory loss and the actual referral to a neurologist. You can ask people at LabCorp and Quest, they are certainly selling a lot more of these Alzheimer's diagnostics.

I think we bought some data suggesting in the last year alone, 300,000 of these tests have been sold.

And the idea would be if you could get that referral earlier because now I have a diagnostic, I don't know how much amyloid plaque I have, but I have some presence and the primary care might say, minimum now is maybe the time to actually go see the neurologist and therefore, increase the yield of patients who are eligible for treatment to actually get one of these appointments.

Terence Flynn Analyst

And where are we in terms of commercial coverage of the blood-based diagnostics because I know that's something that you guys have been working on, but in terms of actually getting insurance coverage for those.

Christopher Viehbacher Executive

I think -- well, once you get -- you can sell a diagnostic if you have a CLIA lab essentially, and you don't need an FDA approval, but you're not really going to get uptake or reimbursement until you get that. And so we are -- we have been talking to a lot of the diagnostics companies. And clearly, we are talking to our physicians about the availability of that. Again, the neurologist is a cautious physician. And I think it will take probably 6 to 9 months to get meaningful uptake of a blood-based diagnostic.

But it's starting to -- I think they're starting to get confidence that they can maybe dispense with the PET scan. And I think the payers might drive that. It's about $5,000 for a PET scan. Last I heard, I think the Alzheimer's test is available for under $1,000 -- so as I look at 2026, we see a confluence of favorable factors here. You've got the subcutaneous for maintenance.

You should have the subcutaneous sometime in the middle of next year for initiation. You've got an increased investment in direct-to-consumer advertising.

And I think a lot of the physicians are now starting to understand ARIA and believe that, that is manageable. And again, if you can get now these earlier-stage patients, and I think Lilly is presenting -- is potentially going to present a first study in presymptomatic. And the odds are that you're going to see much higher rates of CDR Sum of Boxes, you have benefits, although that's not their endpoint. But you'll start to see better rates of efficacy.

We have this landmark study, we and our partner, Eisai, called the HED345. And that will be a truly presymptomatic patients, people with very low levels of amyloid plaque. We believe that Lilly study is actually really just pre-MCI patients. Important though, because I think that will benefit the whole field. But it turns out that if you have plaque at less than 40 centiloids, and we have the AHEAD-3 study looking at that, it seems that at 40 centiloids of plaque, that's where you trigger tau, tau production.

And then the tau production -- overproduction is almost independent of your level of amyloid after that.

Now there, the promise is that we still have to wait several years for that, you could actually potentially prevent Alzheimer's. But certainly, again, if you can catch people earlier because people are building plaques and losing neurons years before they actually demonstrate symptoms. So -- we're very excited about Alzheimer's just because there's now so much data, there's new modalities coming along. You've got the diagnostics, and there are a lot of patients who could really benefit from treatment.

Terence Flynn Analyst

Yes. I just want to circle back on one question just on the market dynamics. It does look like on the prescription data that Lilly has been making a bigger push on market share recently. It sounds like it's more about growing the total market here, and that's what we should be focused on as we go into '26. But can you just talk through those dynamics in terms of share and then also rate of growth for next year relative to this year for the market?

Christopher Viehbacher Executive

We always talk about molecules, but most of us in business are talking about people because it's people who are operating our business and people who are prescribing and people who are patients. And so if you're a sales rep from Lilly, where is the first place you're going to go? Well, you're going to go where Biogen and Eisai have actually already created the care pathways and opened up those. And so that was logical that they were going to go and look for share.

But the real prize is growing the prescriber base and growing the benefit of that drug. And in the second quarter, I think we saw market growth occurring from the efforts of both companies, which is what we've always believed. We've always believed that it was beneficial to have Lilly out there in the marketplace. Every single market that has been created always grows faster when you have multiple players.

Terence Flynn Analyst

So we should expect market growth above what we saw in '25 if we think about '26, high level?

Christopher Viehbacher Executive

That's what we're hoping.

Terence Flynn Analyst

And you think you can deliver at least comparable market share? I mean do you think this shakes out roughly 50 -- I know you're not going to give specific guidance, but is there any reason to think this would be different than a 50-50 split over time?

Christopher Viehbacher Executive

I don't think so. I don't see why. I mean, on the one hand, Lilly offers the once-a-month dosing, and they tried to present this as kind of a one treatment cycle and done. At the same time, now Biogen and Eisai have demonstrated that, well, 4 years after starting treatment, you're still doing better, and we have a maintenance indication approved by the FDA, and we have a subcutaneous form. So why would you stop treating?

And donanemab can't have a maintenance indication. So that is playing out there in that way. But again, -- there's more patients out there than either company is dealing with today. And so we're not so focused on LEQEMBI versus donanemab. It's really around how do we establish this marketplace and get more patients benefiting from these treatments.

Terence Flynn Analyst

Okay. And I want to come to the presymptomatic setting. But first, Novo is going to have some data from their oral sema evoke trials. And I think there's some debate in terms of is that an opportunity for the Abeta? Is it a competitive threat?

Does it increase the total pool of people that are going to be coming on to therapy? So I would just love your kind of latest thoughts on when we do see this data, what it means for the market in the event, let's say, that's positive data?

Christopher Viehbacher Executive

Yes. It's hard to know whether it's going to be positive. one talks to an awful lot of experts. There's some plausibility why it might work, whether it's -- we know that obesity is a risk factor for Alzheimer's. So if you're reducing that.

Second is there seems to be potentially some impact on neuroinflammation. We'll have to wait and see the data. I mean the GLP-1s are the people have said, do you really want to give those to elderly people because of the risk of muscle loss. But I think net-net, it will be a positive because in all likelihood, they will be -- they're not going to be used instead of disease-modifying treatments, but alongside them.

And you might actually see a lot more patients in primary care starting to get diagnosed because these would be available to primary care physicians. And so then you're getting a bigger population of early-stage diagnosis and if they continue to progress, and they end up in the neurologists and on Abeta. So I think I could see a synergistic benefit out of that.

Terence Flynn Analyst

Okay. And again, you talked to this a little bit, but the preclinical setting, I think there's a growing focus on that opportunity here. And as you alluded to, you're running the AHEAD 3-45 trial. Lilly has a TRAILBLAZER-ALZ 3 study. As we start to think about doing cross-trial comparisons, maybe just talk to us about why you chose the design that you guys chose and why you're confident that that's the right approach here?

And then when we see the Lilly study, how much read across is there from that trial to your program?

Christopher Viehbacher Executive

Well, one of the things about these neurodegenerative diseases, it take so long, right? I mean this AHEAD 3-45 study, we started recruiting in 2020, and we expect to have results in 2028. I mean that's the scope of the investment that you need to do in this space. But we do believe that will be a landmark study. We believe that Lilly study is more with patients of higher amyloid burden because that's where their drug has benefited.

And so they're really kind of pre-MCI patients.

Now again, they'll be earlier and every bit of evidence that we have seen suggests that earlier is better. We demonstrated already with LEQEMBI that if you get people with very low levels of tau, so very early patients, now when you look at it after 6 months of treatment, you have 70% of patients who have shown no further decline. You've stabilized those patients. And that is huge, by the way. If you're an Alzheimer's patient, you're a caregiver in Alzheimer's patient, not seeing further decline, and this is amazing.

And this is -- this blows the doors off the 27% CDR Sum of Boxes because that was in a different patient pop. Now he was talking about, okay, we can see a lot, and 60%, 60% actually see some benefit. And that sort of suggests that the neurons are not just alive or dead, but perhaps in a stress-time-frame status that can actually recover if you reduce the pressure that's being caused by the plaques. So we do believe that Lilly should be able to demonstrate also very strong data in these earlier patients.

However, their endpoint is really a time to event. And what you really going to want to know is, is it worthwhile to treat a patient who is otherwise healthy, has no symptoms of Alzheimer's. We don't yet know what the risk of ARIA is in these patient populations. And that's why I think the Eisai, Biogen study is going to be so important because we are looking at those early-stage low levels of plaque and what is the impact on CDR Sum of Boxes? What is the impact on cognition?

Because you're talking about someone who's maybe 60 -- early 60s, they've had a blood test, it's positive. PET scan says, I don't know, 50 centiloids. Do I wait until I get to 70, 80 to treat them? Or should I treat already at 50?

And I think payers are going to want to see that because that's not an inconsequential investment. And staying on the drug then for quite a long time and hopefully maybe never getting Alzheimer's or certainly much later than they otherwise would have. But that's where the real promise is, is really getting patients as early as you can and preserving as many neurons as you can because when people talk about efficacy, these drugs are highly efficacious. We get rid of all the plaques, both donanemab and lecanemab.

But that the issue is that you're dealing with an upstream effect on the neurons. And so your reservoir of neurons is really what's going to depend on how healthy you are. And we can stop the destruction of neurons, but we can't bring them back. So the logic of doing these studies, and that has to be borne out, obviously, by the evidence of the trials, is that if you can intervene before you've lost too many neurons, you will do much better. That is the goal of the study.

Terence Flynn Analyst

And is it possible that we see any data from you guys before '28?

Christopher Viehbacher Executive

We haven't -- we don't think so, largely because you do want to follow all of these patients through and show the benefit of cognition. And remember, you're dealing with asymptomatic patient. So you have to wait for them to progress. And so you don't want to take a chance of looking at that too early and not see the benefit on cognition.

Terence Flynn Analyst

Yes. All right, Chris. Well, I think we're up against time, but always a pleasure. Thank you so much.