Biogen Inc.

Biogen Inc. presents at TD Cowen 45th Annual Healthcare Conference

Monday, March 3, 2025 9:10 AM

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Philip Nadeau Analyst

Good morning, and welcome once again to TD Cowen's 45th Annual Healthcare Conference. I'm Phil Nadeau, one of the biotech analysts here at Cowen, and it's my pleasure to moderate a fireside chat with Chris Viehbacher, the CEO of Biogen.

Philip Nadeau Analyst

Biogen is obviously a bellwether that probably needs no introduction. But nonetheless, Chris, we'll start with your vision for Biogen. What is your vision for Biogen over the next 5 years? How do you expect Biogen to create shareholder value?

Christopher Viehbacher Executive

Yes. Well, first, companies in our space are always on a journey somewhere, right? And usually, you are where you are by someone's vision 5 years ago. And that was really -- the vision was, okay, we knew we were going to face a lot of competition for our MS portfolio, but the Alzheimer's franchise was going to more than make up for that.

First, Aduhelm and of course, we all know what happened to that. And then Leqembi. And so when I came in, the idea was we're going to launch Leqembi and then we have the Sage product for major depressive disorder. And that never came about. And obviously, Leqembi is on a good ramp, but it's not quite what everybody expected.

So -- and then the pipeline was all pretty spicy.

In fact, one investor last week described it as what you might find as a VC-backed pipeline. And so there's been an awful lot of need to kind of tidy that up and move away from just purely neuroscience. And then there was also quite a lot of work to do to really realign

resources with the company, not just take resources out, but shift it from MS to new spaces.

So -- and over the last year, it felt like at the start, well, all we're really going to have to do is go buy some companies to actually rebuild. But in the meantime, we've been able to focus the pipeline. And actually, I think we have some really interesting assets in there. And quite honestly, as a CEO, how you feel about M&A is a direct function of how you feel about your pipeline, to be perfectly candid.

And actually, we started to get an awful lot of confidence in the pipeline. And so the real focus is building out now, first of all, a number of key franchises. We have these 4 products that we launched last year. And each of those products is an interesting challenge. They are from an innovation point of view, exactly what you want.

I mean we're talking about not only first-in-class, but first disease-modifying agent ever in each of those 4 cases. But when you have that, you don't have a ready market. You've got to go build the market. That means a very heavy lift on education. And so we are focused on really building out those.

And then as we sort of say, where do I see Biogen at the end of this decade?

I see us with a very strong lupus franchise. I see us with a very strong Alzheimer's franchise, and I see us with a very strong rare disease franchise in areas like rare kidney diseases, but also including the neuromuscular degenerative diseases. So we've branched away a little bit from just pure neuroscience into immunology and rare diseases. But it's more of a rebuilding organically than, say, I might have said this time last year.

Philip Nadeau Analyst

Maybe to dive down a little bit more deeply into 2 points that you made. I guess the first is on the product portfolio. So your guidance for this year is for revenue to decline by mid-single-digit percentage. Investors, I think, are keenly focused on when Biogen could return to growth. Do you think the current product portfolio, both what's on the market in the late-stage pipeline is sufficient to return Biogen to growth?

Or do you need to look externally?

Christopher Viehbacher Executive

We're going to be playing cat and mouse over the next 3 years with a declining MS franchise and then the new products. So I would say over the next 2 to 3 years, if you actually look at the annual results, it's going to be flattish to low growth.

What I think starts to get investors is not so much our annual operating results of the cards we turn over on our pipeline. I've been in this business a long time, as you well know. And you get disappointed by pipeline more often than you get excited. So you learn not to get overly excited about pipeline. But when I look at what we have got and what data, biomarkers, actual clinical results that we're seeing, I'm actually feeling very good about this pipeline.

Philip Nadeau Analyst

So in light of the pipeline, what is your thinking on business development? I think when you

first came into Biogen, you said essentially, they wouldn't hire me if I wasn't going to do deals. Now it sounds like you're actually more enthusiastic about the pipeline than maybe you had been in the past. So how much urgency does Biogen feel it needs to add to the portfolio to in-license or acquire another asset?

Christopher Viehbacher Executive

Well, I'll tell you, what I'm actually really interested in right now is I think we have a really great opportunity to rebuild Biogen, which is an iconic company in our industry. It's still the -- I mean, it's the founder of Kendall Square. It's a company that really with Genentech got the whole biotech sector started. And I think -- okay, now it's fallen on harder times, but I think we can actually really build a great company here.

And I also see an opportunity to fix some of the sins of management that we see in our business. One of the things that we do is we tend to buy our way out of problems in this business, and we don't go back and really fix things fundamentally. So one of the areas is research. And we are just as guilty of some of these sins as any other company.

We've been spending $300 million a year on just basic research. Biogen does foundational research. So over 10 years, that's $3 billion. That's kind of the equivalent of 15 venture funds. Now I could have done a whole lot better just putting that money into 15 venture funds.

And so either we have to do things differently in research or I can't spend that money. And we took a very radical view. We literally cut this in half. And we only kept enough to keep enough assets to get us to 2 or 3 INDs per year.

But research has now become a source of innovation, and it's not just doing foundational research. But it's a whole lot better to bring in assets at a pre-GLP tox stage and shape those than spend billions of dollars all the time on late-stage assets because we've been spending on R&D and it didn't work.

So there's a whole area where we're taking more of a venture type approach and a venture discipline and portfolio management approach to research. Now that is not going to drive our share price over the next 5 years. But as they say, the best time to plant a tree was 20 years ago. Today is the next best. And so somebody at some point has to get back and start rebuilding from scratch.

And so sometime 10 years from now, one of my successors is going to benefit from that.

But you got to still get back to what we're supposed to be doing, which is innovation. And then the next piece is, we have a good pipeline, but as I've discovered, you can never have enough pipeline in this business. And so the next priority is really building the substrate for growth. So that's stoke-like deals. That's HI-Bio-like deals.

They are not going to launch in the next 2 to 3 years, but we have a lot of conviction around those assets because of the nature of the data and the disease areas that they're addressing. So that's the second priority.

And then the third is we are constantly on the lookout if we could find another Reata type deal where there's something that is immediately accretive. Yes, we would do it. But the problem is

that those deals become very expensive, and it's harder to make that work from a shareholder point of view. And my motto has always been, I'm paid to make our shareholders happy, not someone else's shareholders.

So we are not going to abandon our financial discipline just to try to do some window dressing on the balance sheet short term. And I don't think we need to. I mean it's not -- I don't think we're really declining. I'd like to see us grow more. But I think we have to kind of keep our heads down, execute and really bring this pipeline to market.

Philip Nadeau Analyst

One big picture question before we dive into some of the franchises specifically. It seems like there's a lot of changes going on in the biopharmaceutical industry these days. We're seeing unprecedented things, for example, coming out of Washington. You've been in the C-suite for a long time. Could you maybe give us some of your wisdom?

How has the industry changed over the last 10 years? And what hasn't really changed? What continues to be constant?

Christopher Viehbacher Executive

Well, I think there's a couple of different things that certainly have changed. One is, I mean, just the nature of science has changed. The level of precision medicine that we have is completely different than the biomarkers, the genetic testing that we have, even the evolution of AI and how we can use data in research and development, things like gene and cell therapy are having unprecedented ways of actually working, even though they're still some ways away from real commercial impact.

So the science of that is interesting. And you're also getting into much more expensive therapies. And so when you look at the Medicare budget now, you're seeing an awful lot of these medicines really consuming a lot of those budgets. And of course, as we have shifted from small molecule to large molecule, that has also had a major impact on budgets because we used to have a situation where I remember when Plavix went off patent. We went from a run rate of $6 billion a year in the U.S.

to $100 million within 6 weeks. Well, that kind of drop actually creates the space in payer budgets to fund innovation.

Then now you had the Humiras of this world coming along. And even today, post patent with multiple biosimilars, I think they've lost something like 20% of the volume. So there hasn't been the kind of the turnover in the portfolio. Everything is additive. So from the payer point of view, this has become much more of a challenge, and that's why we're seeing some of the legislation like the Inflation Reduction Act.

And then the other major change has really been the rise of PBMs. I mean I can remember when and pharmaceutical companies own PBMs, and we sold them, and they played a role. And now today, you have PBMs that are not just PBMs, but they control huge numbers of pharmacies and physicians and have become a major, major force out there in the marketplace.

And so as we sit here today, I say there are a lot of financial forces at play that really can affect the future returns of what our investments in R&D are. And I think one of the response is going to have to be we have to really get to figure out how to do R&D a lot cheaper because one of the things that has not changed is how we do R&D.

We are still spending a lot of money on research. We are still spending a lot of money on clinical development. If you're going to do a 400-patient study, you need at least 450 sites. Now who would design a model like that? That's kind of crazy.

And we are already seeing, for instance, we have used at Biogen AI to create virtual waiting rooms.

We had a major hospital chain said, we really like your lupus drug. But we don't think we have any more patients. Can you help us? And so we took their anonymized health care records, and we actually used AI to go look through social media as to who was really complaining about lupus and exchanging views from a patient point of view, created a virtual waiting room of 50 patients. We couldn't access those.

We had to go give those to the hospital, but it dramatically improved the productivity.

I mean you're talking about 1 patient or 0 patient per site, and now you're creating a virtual waiting room of 50. That's the type of thing that I think we need to do because that commercial return is going to continue to get squeezed. You look at Europe with 0 economic growth in Europe, means their tax base is basically growing at 0, and that's what funds their health care system. So I think we really are going to have to focus on becoming a lot more effective at how and efficient that we bring R&D to market.

Philip Nadeau Analyst

That is very helpful. Maybe to dive into the franchises, Leqembi, can you talk about the status of the Leqembi launch in the various markets and how you see the launch progressing?

Christopher Viehbacher Executive

Yes, I'll start off with Japan. I was in Japan last week actually, and that is going extremely well. And it was quite interesting because we had a Saturday, we spent at a huge meeting of almost 1,000 physicians from across Japan. And there are still an awful lot of the same bottlenecks that exist here. I mean this is still a heavy lift for physicians with the MRIs and the PET scans and the infusions.

It is a little easier in a single payer system because you're not negotiating with the different parts that control these interventions. But I would say it is a more concentrated population. And so the education has been better.

The really interesting thing is that we are learning more about Alzheimer's every day. I mean really, the Clarity data was not only the first disease-modifying data, but now we're looking at, well, who's the right patient and who's going to benefit from these different interventions from a modality point of view, but also stage of disease point of view. And so there's an awful lot of interest in that in Japan, and that's going well.

China is going also extremely well. This is a private pay market. So there's no government reimbursement here, but that has also gone extremely well. The U.S., I think, is still in facing some of the bottlenecks to treatment. We've always said we've got -- we don't have a demand problem.

We have a constriction on the supply of treatment. That improves every day, but it is a heavy burden because there the neurologist -- if you think about 500,000 new patients being diagnosed with Alzheimer's every year and 13,000 neurologists, do the math.

This is going to be an issue if we can't improve the productivity of the neurologist. And the neurologist was busy before and now negotiating where am I going to go get the PET scan or the lumbar puncture, I got to schedule these MRIs. Now I need 3 of them in the first 14 weeks of treatment. I need the MRIs, and I've got to understand how ARIA works. And each of these is a friction point in the system.

They've got to go negotiate. I mean the infusion beds are available to all, obviously, but are really seen to be the domain of the oncologists and hospitals start to do the math of, am I better treating an Alzheimer's patient or am I better treating an oncology patient. And people are literally doing spreadsheets and trying to justify the financial returns to be able to access the infusion beds.

So a lot of friction points. Now we are doing a number of things. Obviously, the practices themselves are getting better protocols, hiring nurse practitioners to do some of these things, keeping the neurologists just for making sure they're doing the diagnosis. The -- getting the subcutaneous formulations will be a huge thing first for maintenance. So we have a PDUFA date at the end of August.

We have -- we're expecting somewhere in early 2026, subcutaneous for induction. Actually getting the blood-based diagnostics will be important. Roughly half of the people that present to the neurologist are not actually eligible for treatment because they're too far advanced.

So if we can actually also engage primary care and also use these blood-based diagnostics, which we think will get FDA approval sometime midyear, we could actually even eliminate the need potentially for the PET scan or the lumbar puncture. But you also are going to potentially be able to triage the patients even before they get to see the neurologist so that when the neurologist is in front of someone, it's more likely to be someone who is eligible for treatment.

So there are a lot of things that can be done to enhance the productivity. But we gain new prescribers, new sites every week, every month, every quarter, and we're seeing that quarter-on-quarter growth all throughout the year. And I think that's what we're going to see. I think the blood-based diagnostics and the subcutaneous for induction are probably the 2 things that could potentially accelerate that growth beyond where we are.

Philip Nadeau Analyst

How do you view the current and future competition in Alzheimer's? And is there an opportunity to differentiate Leqembi through initiatives like the subcutaneous version that you mentioned?

Christopher Viehbacher Executive

Yes. So right now, actually, we haven't really seen that much impact from Lilly. And I think that just goes to actually Lilly is seeing the same bottlenecks that we are. And I don't think we need to be overly focused on the competition. I think we both need to be focused on growing the market.

Lilly's product is unique in that it only addresses aggregated plaque, and you can really only stay on treatment for a limited time period before you get these antidrug antibodies.

Now -- so the theory that you could just go on for a year and be done, I think, is undermined by the fact that we are now having a maintenance indication. And the reason for that are these protofibrils. And that was actually one of the things I saw in the 6 hours of presentations in Japan. I think as a company, we need to tell more of the story of the protofibrils because those are really the toxic part of the plaque. They're soluble.

You can't see them on a PET scan, but you can see them on an electron microscope. And that is where Leqembi is different than donanemab.

Donanemab only goes after the aggregated solid plaque. And that's why you have to stay on treatment. But I think the bigger thing is also who is the right patient. You hear this statement, well, modest efficacy. Well, the reality is it's not modest efficacy.

We actually get all of these plaques to undetectable levels.

The question is for whom is that really the benefit. And I think we're moving in a little way that oncology did. I used to say, well, you're only getting 3 months of survival. But when you actually looked, there were patients who would live another 2 years. There are some that wouldn't live at all.

And so getting more precision neurology, if you like, I think, is coming.

We already see, for instance, if you look at patients with low tau, so early stage. Well, after 6 months, over 70% of those are stable, have stable disease, not slower decline, no decline. And 60% actually demonstrated a benefit. Nobody has ever seen anybody actually improve before. So that's also a set of data that we have.

Lilly did not do a stratification of low tau patients. And so we have that data. And that says, hey, forget this 27% CDR sum of boxes here. And then the other piece of data that we have is this 3-year data where we clearly show that those who have been on treatment are doing consistently better 3 years afterwards than those who stopped treatment.

So the first year was really around focusing on the safety, the care pathway, the reimbursement. There wasn't actually an awful lot of opportunity or even time or even brain bandwidth for people to talk about the benefit. And so we are now shifting gears in our commercial approach to be able to really go after this data, the early tau data that really demonstrates a really compelling efficacy profile, the protofibrils versus the plaques and then the long-term maintenance therapy, plus you have all the subcutaneous formulation. So it starts off not what everybody expected in terms of other launches, but we're doubling down on Alzheimer's. This is going to be a significant market.

Philip Nadeau Analyst

We, at TD Cowen, project $3.4 billion in Leqembi revenue in 2030. How does that strike you? Is that conservative, aggressive? And when do you think ultimately Leqembi could begin to contribute to Biogen's top line in a meaningful way?

Christopher Viehbacher Executive

We started off with a market that had wild expectations. And in fact, when we launched, we were trying to say, look, this is going to take some time to build. Biogen had the experience from Aduhelm. So I think where we started was the market had higher expectations than we did. I would say the reverse is true now.

I think the near term are reasonable expectations, but I think we have much higher expectations for the longer term than the market does. I mean you've got, like I say, 500,000 -- now part of that was -- everybody talks about the 20 million or the 30 million patients. That's not really accurate because there are a lot of patients for whom this treatment is not going to work.

If you are just too far advanced in your disease, too many neurons have died, we can't bring those back to life. But I think when you start looking at the AHEAD study, where we're going to be looking at presymptomatic and Lilly has a study in presymptomatic, you're looking at now the low tau really early-stage patients and the maintenance.

It's still 500,000 newly prescribed every year, and that's expected to grow to 750,000 over the next 10 years. So there is clearly a market. There's clearly a need. And the most important thing is people forget, Alzheimer's will kill you. Alzheimer's is a fatal disease.

It is already the biggest single killer in the U.K. and is one of the top 10 causes of death in America, particularly amongst people over the age of 65.

Philip Nadeau Analyst

Moving to SKYCLARYS. Can you discuss how the SKYCLARYS launch is progressing here in the U.S. and overseas? And how do you consider competition if anything?

Christopher Viehbacher Executive

So this one is -- generally, you have a set of patients that have been diagnosed, nothing was available in terms of treatment. And so as you go market by market, the U.S. and now we're in Europe, and we expect approval in Latin America this year, you get a first early bolus of patients.

And when you actually track the SKYCLARYS launch versus other rare diseases, it is best-in-class launch. So this actually outperformed even the SPINRAZA launch when you look at the offtake. And SPINRAZA was already a best-in-class launch versus a lot of other rare disease launches.

Now what you have, and I learned this many years ago when I was at Sanofi when we acquired Genzyme, the secret to marketing in rare diseases is hunting for needles in haystacks. You've got to go find the patients. And there is a large prescriber base for a very small number of

patients. And we are now looking at using -- we've been using AI.

We're using some of our MS reps. We're actually using some not direct-to-consumer, but there is some media-based education that because quite often, a lot of people have never heard of Friedreich's ataxia, including physicians. Some of these patients are in primary care or pediatricians or cardiologists and so you have to figure out an efficient way to go after those physicians.

But we've seen a very rapid uptake in Europe. Now we have -- we get ahead on numbers of patients than revenue because we're putting them on early access programs and then we go and negotiate. So a lot of the revenue increase that you're going to see is the ability to actually now convert those patients from free drug to paying drug.

And then the same will be true as we move into Latin America, Middle East, Turkey is a major market. So it's going to be a steady growing business. And I think certainly, somewhere potential, I would say, $1 billion to $2 billion that over time, over the years should be possible when you look at the numbers of patients.

Everything that we've seen, we thought there were 4,500 patients in the U.S. There's probably 4,800 when we do an analysis of claims databases. Now finding all of those and some of those are older than people thought.

There was kind of this belief that you died in your 30s. We're actually finding patients in their 40s and 50s, even a 70-year-old. And those are people who've been on the -- have had this disease for a number of years and lived with it. And so the equation for treatment is a little different than sort of someone who's newly diagnosed.

Philip Nadeau Analyst

Maybe a minute on the MS franchise. What is the outlook for that franchise? Is a modest contraction reasonable in light of all the competition that is coming? How do you think about resourcing the MS franchise? What is the appropriate amount of marketing promotion to put behind the products?

Christopher Viehbacher Executive

So I went back and had a look at the last 5 years. On average, we have lost $700 million of top line every year. Last year was actually a little less largely because we were able to regain some market share for TECFIDERA, but that's about seems to be the rate.

Now what drives that, first is the timing of a launch of a biosimilar in the U.S. There is one approved, but it has not yet launched, and you may have better information than I do about when they're going to launch, but that will have an impact in the U.S. There is kind of an interesting situation with the assay because, as you may remember, there are cases of PML that have been associated with Tysabri. And so you need to have an assay for JC virus. And so it's not a simple launch for someone to do.

And then in the Europe, we were successful at defending our market exclusivity. You have data exclusivity and then you had some extra data protection and then you have this market exclusivity of 2 years. That expired in February, but we were also successful in defending a

patent that goes to 2028 in Europe.

And now we have to make sure that every single European country actually respects that patent because, as you know, Europe is a complicated place. You can win at a European level, but then you've got to go defend that at a national level. So the rate at which it declines is a little dependent on those factors.

And that's, I think, why we've been prudent in giving guidance this year. But one of the things we have done is pretty much removed all of the resource in U.S. and Europe, except for some resource, which we want for the Leqembi launch because there's an awful lot of overlap between MS prescribers and Alzheimer's prescribers.

Philip Nadeau Analyst

And one last question as we're just about out of time on the R&D portfolio. You mentioned that you feel like there's an opportunity to rebuild Biogen. What is the optimal structure for an R&D portfolio as you think about that rebuild? And for investors, there's one pipeline program we should diligence. which one do you think it is today?

Christopher Viehbacher Executive

Well, first, one of the things that we did not do at Biogen is really the classic drug development. If you're in neuroscience and especially when you're in neurodegenerative diseases, the slow rate of decline of patients means that you really can't do a Phase II. So in essence, every Phase III first is a proof-of-concept study. They are many years long.

I've never seen so many Phase IIIs that are 5 years or more, and they're very costly. And so I think what you really -- what we're trying to do is focus more on diseases where we understand the disease biology.

Second is that we can do derisking in a normal way where we can get actually a good read on efficacy and safety in the Phase II.

And three, move into areas where we don't have to necessarily do 5-year studies to see if something is working or not. Do we have a biomarker? Do we have a clear endpoint? Is there a clear marketplace already? And if you take felzartamab as an example, that's a terrific example.

We have very high confidence in the Phase II data we've seen. They are clearly defined markets, and those studies can generally be done within 2 to 3 years.

PMN will take probably a little longer with 4 years. For diligencing, I would go look at lupus. There's only 2 approved drugs for lupus. So I don't think there's really been an opportunity for the investor group to really go do a deep dive into lupus.

I see people saying, "Oh, well, these drugs have not caused relapses." This disease is a whole lot more complex. We had a panel of 4 patients at our executive leadership offsite. As one patient said to another, my lupus is not your lupus. This is a very heterogeneous disease. And there are going to be a lot of different points for demonstrating efficacy.

CLE is very different from SLE and then you got lupus nephritis. But it's a huge market, 5

million patients around the world. And we think we're particularly well positioned with positive data on dapirolizumab in a Phase III, which we're now replicating. And we feel very good about Litifilimab, and we have felzartamab in lupus nephritis. So it's going to be a major franchise for us.

Philip Nadeau Analyst

Great. With that, we're out of time. I like to thank you for an interesting discussion.

Christopher Viehbacher Executive

Thanks, Phil.