Biogen Inc.

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Eric Schmidt Analyst

Good afternoon, everyone. If you could take a seat, my name is Eric Schmidt, and my pleasure to host this next fireside chat with Biogen. We're delighted to have with us today Chuck Triano, who heads the IR group there at Biogen. Chuck, thank you very much for joining us.

Charles Triano Executive

My pleasure. Thanks for having me, Eric.

Eric Schmidt Analyst

And I think probably everyone in the room is somewhat familiar with Biogen. But why don't you give us just 2 minutes on kind of what you think is top of mind at the company today?

Charles Triano Executive

Sure. Yes. Yes. Thanks, and good afternoon, everybody. And quick safe harbor statement.

Obviously, there'll be forward-looking remarks. So actual results, as we know, may differ from those remarks.

But I think if we look at Biogen over the last couple of years, the change in leadership, change in board composition, governance, and I think a renewed focus on driving returns for shareholders. So in business, to help patients, of course. In business to generate an attractive return for shareholders, I think that's a nice add-on to the view. So the focus had been a company that was declining in revenue. And while the revenue was declining, the cost

structure really didn't move.

A company that generally swung for the fences, high risk, high reward, that many times didn't pan out.

And so what we see today in terms of top of mind at the company, I'd isolate -- maybe not isolate, but I would talk 3 general areas under this heading of driving returns for investors: stop the decline in revenue, flatten out; manage the cost structure, which we're in the midst of a savings program, and we can talk some more about that; so returning to growth ultimately on the top line, leverage that from top -- leverage to the bottom line from both top line growth, profitable top line growth, and the cost structure. And then really, I'd say, augmenting the portfolio. We've had some recent failures and recent attrition of what I think we would all say were indeed very high-risk programs.

And so not that we're moving away from anything high risk, but we're making a conscious effort to augment the pipeline with programs, and I'll define what we mean by programs. It may be more a bit traditional in lack of a better term. And what we mean by that is adding program -- and I think the HI-Bio acquisition could be an example, where you have proof-of-concept data in hand. Oftentimes, particularly in neuroscience, your proof of concept often doesn't come until your big, expensive Phase III study. Looking for programs where the endpoints in Phase I were consistent with Phase II and are consistent with an established regulatory pathway.

So you have an idea of what Phase III should look like as opposed to programs where you are looking to be the trailblazer.

Say never been approved, there's never been a pathway, hopefully, regulators will agree with some ideas here. So not that we don't take risk, but augmenting the program to have a more balanced risk profile for Biogen. So all of this goes into, again, returning to top line growth, work the cost structure so the top line growth can leverage to the bottom line, and then sort of a refresh on the pipeline.

Very good people, very good leadership team, focus on shareholders and being shareholder friendly and generating those returns at shareholders. And it's a process, right? It's a process. But the mindset, the mindset, I think, has really changed in terms of what Biogen is all about. So we haven't walked away from anything.

I think we've enhanced and added some focus points.

Eric Schmidt Analyst

Okay, music to my years. I'm a stock guy, you're a stock guy. Let's talk a little bit more about the stock. From where I sit, some of what you just laid out is certainly on the right path. You have stabilized the top line.

You have cut the cost. You have re-prioritized certain pipeline programs. Yet the shares themselves, the stock is certainly near its all-time lows or most recent lows. What doesn't resonate with investors? When you talk to folks either at our conference or others, what are they reflecting back to you?

Charles Triano Executive

Yes. Yes. So it's always tough so I'll give some opinions, who knows what, but the market will figure out the stock price over time. But I think a bit of perspective and a lot of this goes to the LEQEMBI launch. So an approval for Alzheimer's, gee, that sounds like it should be pretty much off to the races in terms of a launch.

And sounds great, we've been waiting decades for something. And if I just contrast, when I joined Biogen earlier in 2023, and I looked at sell-side mean, I won't say consensus because numbers were all over the place, but what were 2024 sales of LEQEMBI going to be globally in 2024, so going back to February '23, so people looking out another year, the mean was over $500 million. If you look at that, what is the 2020 forward estimate today, I think it's $220 million.

So I think part of this has been, let's call it, a reset. And I think not anything that anybody said wrong, but I think there was an expectation of an Alzheimer's launch, this should be pretty easy. And what we've been talking with investors about and learning ourselves, but the view, as you're well aware, this was a launch that did not go into an already established arena where the capacity is there, doctors clamoring, all ready to prescribe, even though there's several steps along the way. There really was no dementia care in this country and certainly no infrastructure to support it.

So this has been, and we've talked about this, this is a building the market, building awareness from patients and caregivers, building enthusiasm with neurologists who typically are not big prescribers of drugs, especially for Alzheimer's patients, where their usual reply is, I'm sorry, I think you're diagnosed with Alzheimer's, there's really nothing I can do.

So it has taken time, and I think we saw this reset. So one big thing, and we'll talk more about that with investors, I think, is a realization that indeed, this is a build-the-marketplace endeavor. It can and should be a big market in our view. But it's not launching into the primary care arena, in oral, to a captive audience, and saying we're ready to prescribe from day 1. So I think that's point one, Eric, and a lot of talk on LEQEMBI as it should be.

This is -- this can be a great value creator.

Two, I think business development. Biogen, for a while, had not done much in terms of meaningful BD. We've had the acquisition of Reata and the acquisition of HI-Bio. So I think, the Street is, in our view, getting a view that there is discipline. These, I think, have been well received by the Street.

But what else can Biogen do? We've got the launches ongoing today. We know there is a bit of a gap mid-decade, and then HI-Bio and some other -- BIIB080, some other compounds may come to market later in the decade. So talking about can you bring in profitable revenue mid- to late decade? So maybe another leg of the stool in terms of talking about another potential growth driver.

And like any public company, of course, we have an obligation to look. We actively look at anything that can be value creating. So I think that's a big part of it.

And one area that I'd say we do talk a bit about it, I think, maybe not as much because LEQEMBI often drowns things out, but the cost reduction program. And just as a quick for instance, if we looked at our last quarter that we reported, and obviously in the midst of launching LEQEMBI, SKYCLARYS, ZURZUVAE, we were able to pay for that incremental SG&A through our Fit for Growth program. And a little bit -- like even internally, you talk about the importance of culture. You bring this to an organization and say, this is how it works if we didn't have Fit for Growth. And Fit for Growth was, say it this way, maybe cutting waste.

Because remember, we -- out of a base of maybe 8,700 colleagues, we cut 1,200. We took out a whole layer. We were spending money on nongrowth areas, so redeploying to growth areas.

But when you explain even to the colleagues internally, if we didn't have that program, the launch expenses would have been ex $100 million more. Translate that to EPS, right, being a stock guy, lower EPS, give it a P/E and stock price impact. So I think also the leadership team has been doing a good job, helping colleagues understand what drives value with shareholders. And it's not mutually exclusive to drive value for patients and for shareholders. So again, back to that ownership mindset, I think, has been important.

Eric Schmidt Analyst

For those of us who aren't on the inside, what was left on the cutting room floor with regard to the $400 million in cost savings under Fit for Growth? Is there anything that you don't have capability-wise? You've talked about supporting these launches, which is a new capability. What can you no longer do?

Charles Triano Executive

Yes. I think we cut waste. I think the big part was cutting waste, span of control, layer of management. Stroke program is I think -- I don't want to call it a poster child, but let's, for lack of a better term. That was a program that was difficult to enroll, right?

The market was starting to move away. Oftentimes, in pharma, let's keep spending money until someone says, don't. So I think some of those programs that really did not have a realistic risk reward, a shareholder focus, were cut.

We were spending 40%, 45% of our marketing effort on 5% of the growth. There was a bit of a fear that if you back off too much from some of the legacy slow decliners, you would plummet. Didn't happen, right? But I think it was the guts to say, well, let's try it.

So we have not given up. We've refocused. We've brought in a new Head of Research, Jane Grogan. So that's for 10 years out, but I think a focus on the highest-probability programs and not just we go where no one else goes. Because the feedback from shareholders in my first 6 months was, that attitude is okay, but it hasn't delivered value because there's a reason.

Sometimes, too much risk doesn't equate with...

Eric Schmidt Analyst

Nobody's there.

Charles Triano Executive

But yes. But Eric, we haven't said we were good at something, we're no longer good at that. I think it's been really refining and putting more focus on those areas we see going, and very conscious effort in this. It takes a lot of coordination internally between research, development, leadership, to say we all agree that we're rowing in the same direction.

Eric Schmidt Analyst

A lot of work to make those cuts and a lot of bravery for sure. Chuck, let's go deeper into LEQEMBI. You talked about the reset that has happened there. Are we done with the reset? Are expectations appropriate?

And you've also spoken to sort of a steady growth curve as opposed to any sort of accelerating growth in the future. Why shouldn't we be a little bit more optimistic to see acceleration?

Charles Triano Executive

Yes, yes. And I think it's interesting, every meeting that we do with investors, question one and question two, where is the inflection? And I think it's important to talk about a Wall Street inflection, which is a hockey stick -- that suddenly, the lights are switched on and off to the races, henceforth and forevermore. Versus what we are seeing, which is a slow, I think, bending of the curve, and let me tell you what I mean about that.

The fact of the matter is, what we're seeing is we talked about no infrastructure to treat dementia patients. We're seeing that infrastructure build, and that build has been driven by demand awareness as opposed to big centers saying, we're just going to start building the infrastructure and hope they come. It's been the other way around. Until patients are coming, our caregivers are asking about it, it's been a bit slow. And if you look at 2 different aspects of this, one is the integrated delivery network.

Now you're talking protocols, in some cases, a business model, a business case. You're talking about perhaps, in these large systems, starting with one doctor. Say Dr. Schmidt worked the protocol with 5 or 6 patients, come back, tell us where the friction points are. So you may have to tweak things, but you come back.

Once that's been kind of settled and tweaks made, we're seeing those centers say, okay, let's bring 3 or 4 more neurologists into the program.

And then what we've been seeing also with the integrated delivery networks, after that happens -- now this is over a period of time, as you can see. The next step is we've got a pretty good rhythm at the home office, for lack of a better term. Let's open up some of the trial sites. Let's go out to our Queens affiliate and start opening and use that protocol.

But the fact is that the integrated centers go at different rates of speed. And we like to contrast this with oncology. If you had oncologists, right away, let's go for the latest, greatest, get all my patients in. We talked earlier, neurologists just are a different type of prescriber. So what we're seeing at different rates of progress, the centers are slowly coming online, slowly expanding and extending.

And in the meantime, where we're seeing some, maybe I'll call it, easier writing has been with the smaller unaffiliated practices that don't need to write a business model, that don't have to go through a lot of red tape internally. So some of those physicians early on were indicating to us, we'd like to see a rep. We're ready to go here. So that's why recently, we have added sales force, Biogen reps. Some focus is on the smaller practices saying we're ready to go, but also working on the integrated delivery networks.

We have not seen any of the Biogen reps who are trained in this area, many have prior experience with neurologists, we have not seen any doors not opened to those reps. And so what we're seeing, Eric, is a slow view at different times, where the IDNs are steadily increasing. And once you get that tipping point, where we had one doctor, now we have 2, now we have 5, that's probably where you see this bending of the curve. Most recently, maybe a couple of months ago, if I look at the prescribing, it was actually the majority was by the unaffiliated doctors. Perhaps, 60% by unaffiliated, 40% by the IDNs.

We expect that is going to invert at some point, so that's what's driving this. The other thing, and I think, as we all know, being in the industry for a while, experience. Physicians' experience looking at ARIA. There, they have patients on the drug long enough where they can start to see some clinical outcomes. And physicians tell 2 friends, tell 2 friends, speak from experience.

So I think all of this directionally building, we keep at it.

And our job is to not just motivate patients and caregivers but the physicians as well because this is not a natural occurrence to them to right away start treating Alzheimer's patients with something brand new. But we're getting there. We really haven't seen any centers go the opposite way, saying we tried it, but not working. So the Wall Street hockey stick, we've kind of tried to dissuade, but said -- but yes, bending of the curve and momentum building, that's what we've been seeing in the field. And the other thing, going back to your earlier question, there's no proxy for this launch.

So even internally and for the analyst community alike, well, what would we look at to say, oh, this is how you model it, and I can tell if you're doing better or worse. This is new for everybody. So even the partnership learns, and that's why, I think with Biogen somewhat in the lead, so we have an opportunity to add some reps here and get to some docs willing to prescribe. Doing more awareness building, all of these things will come. We didn't want to do too much before the infrastructure was sufficient enough because you don't want to fill up waiting rooms.

So it's all building, but directionally correct. But this, I think, has been part of the story. But it is in response to, when is the inflection? Is it this week or is it next week?

Eric Schmidt Analyst

Well, absent that inflection -- and this launch has had its challenges you just laid out, Chuck. Absent that inflection, of course, investors can't be confident that we're going to get to here, right? You mentioned earlier that this is still going to be a very important drug. You think this is a very large market. You think we may end up in the same place just through a different path.

What do you think is the most important or most -- for you, as someone who speaks or thinks all the time about LEQEMBI, what's the best ray of hope, the best beacon of light, to think, you know what, at the end of the day, this is a multibillion-dollar drug?

Charles Triano Executive

Yes. Yes. I think what we are seeing in actual practice is in our good results here and physicians' willingness to learn. A lot of it is, I'm interested, tell me how to do this as a neurologist, right? There's a PET scan and you've got to look at that, right?

Then you've got to screen the patient, and then you've got to determine then you've got to get...

Eric Schmidt Analyst

That receptivity.

Charles Triano Executive

Yes. So receptivity, and I think all of that continues to build. So that's why I say no one's going backwards saying, it sounded good, but we don't think so.

And then there'll be some other metrics. I think timing will be nice in terms of potentially maintenance therapy, subcu. I mean you get a subcutaneous formulation, you can negate a lot of need for PET scans and infusion chairs as well. So I think all of that is building with the story. So I think that gives us continued confidence that this gets there.

Eric Schmidt Analyst

Okay. We've got another drug in the marketplace, Kisunla, donanemab from Lilly. Is it too early to say what you're seeing there? Or what are you seeing from...

Charles Triano Executive

I'd say it's too early, Eric. We all look -- we can look at prescription data. I think, in the first 7 weeks, Kisunla had maybe 1/3 of what LEQEMBI had. But again, we were first to market. But no, nothing that we would look at today and say there's a distinct avenue that we have to speak about here.

I mean we've been -- I think there's been good receptivity to what the longer-term data Biogen and Eisai presented at AAIC because the question with Kisunla, and there will be -- this market is plenty big for several kings, probably.

The questions remain. ARIA, we know, is a big issue with doctors that they have to get their arms around. Stopping, right? When -- what happens after you stop a patient's treatment? It's interesting that the data that I just referenced that Eisai presented at AAIC, 36-month follow-up, there's still a benefit.

The belief is that the plaques and the biomarkers slowly return. I mean, you can certainly stop LEQEMBI because that new data is not in the label at this point. But I think it gave doctors another view of, okay, and we've seen that -- we've seen experience with Aduhelm even.

Patients are afraid to come off of it because they've seen a benefit. So we'll continue to look.

I think overall, history does say when you have another big player come into an emerging market, it generally is a rising tide. The tide doesn't rise immediately. It's not like Lilly comes in and suddenly, there's 9,000 new neurologists that show up as well. But I think over time, they'll get share, but then I think build awareness of the marketplace.

Eric Schmidt Analyst

Makes a lot of sense. One headwind that you've had to face in the last couple of months is in Europe, where we had a negative CHMP. So tell us where we are in the process in terms of hoping to reverse that.

Charles Triano Executive

Yes. Yes. We were surprised on that view. And so where we are now -- and there's a pretty specific process here in Europe. There will be a reexamination.

New rapporteurs have been assigned. That was -- the identities, we haven't talked to the identities. But that was in the minutes of the CHMP on the website that new rapporteurs have been assigned. So they will have a discrete window, typically 60 days, to rereview the data.

Eric Schmidt Analyst

You've already asked for the reexamination, so that clock has started?

Charles Triano Executive

Yes.

Eric Schmidt Analyst

And have they said when the 60 days...

Charles Triano Executive

We've said it's in the calendar fourth quarter. So the re-exam will start. The question that we've had, and this is how we've answered it, could you put in that 3-year data? The rules are, no new studies, but we are going to ask saying, this is not technically a new study. It is an extension of an already existing study that, in fact, was part of the initial review.

So we'll see how that goes, but...

Eric Schmidt Analyst

You don't yet know whether you'll be able to include the additional [data].

Charles Triano Executive

That's right. That's right. But we will ask on that front. So you'll have a new set of eyes. We know in Europe, there's been, I think, letter writing by medical communities in support of benefit risk.

When you look at their public statement, it appeared the opinion that it was more -- it was not about the drug doesn't have any effect. It seemed to be more a balance of benefit risk, noting ARIA rates. And as we know with -- I mean, you can look at labels in the U.K. as an example. Not to say there has to be a parallel, U.K.

said let's limit some patients. So there are certainly avenues that could be discussed with regulators. But the view is we'll have an answer in the not-too-distant future. So hopefully, it's positive. If it's not, then you withdraw and you have to start over and decide, do you want to put in a whole new application and start from day 1?

That will be a bridge to be crossed if it needs to be crossed. But yes, it's a pretty short order, Eric. We will communicate...

Eric Schmidt Analyst

And from an investor standpoint, you're committed to just announcing that decision when that happens? So that will be a press release whatever happens?

Charles Triano Executive

Yes. That's right. That's right.

Eric Schmidt Analyst

Thank you for that. Maybe just give us an update then, Chuck, on the subcu. Lay the land for us there and what's the...

Charles Triano Executive

Yes. So we've got a couple of approaches with subcu. The first one underway is subcu maintenance, so this would be 360 milligrams weekly. And we are in the midst of a rolling submission. The one remaining data point to put in there is a immunogenicity data point.

We expect that will be ready by October to submit, and that will hopefully complete the filing. At which point, we'd get a PDUFA date. So if it's fast or if it's expedited, it's an 8-month. Otherwise, it's a 12-month.

So I think either way, subcu maintenance, if all goes well, would be a 2025 event. And then on the subcu -- and I think the timing of that would be fortuitous given at that point, you'll have patients. And again, whether you switch from an induction to a maintenance protocol, this is TBD. But 18, 24 months, that will be discussed with the FDA, but you'll have a lot of patients cycling off the induction through IV around the same time frame. So I think the timing there could be good for a maintenance view.

And then on induction, the partnership actually had looked at initial dosing that was a bit higher, where we ran the bioequivalence. And what we saw, even though numerically slightly different, but we saw ARIA rates perhaps a little high. Efficacy, a little higher. We don't think statistically different from the IV. But the thought was given that ARIA is most risky or most likely to occur in the first 6 months and given that the initial dose looked at for induction with subcu maybe over-indexed a bit on efficacy, the partnership, not -- the FDA did not come to us and say, change it.

The partnership said, let's look at a lower dose. We might make a better patient experience in induction where you are going to deliver plenty of efficacy, less drug, perhaps lower ARIA, less drug in terms of what you need in the pen.

And so we are currently doing some modeling and looking at a dose lower than the 720 milligrams we initially had reported out on. We haven't announced what that dose is, but the thought is that we should be able to get a filing in early part of next year for the induction. And again, it still would be a weekly pen here. But we're looking at that for the overall patient experience. Right now, generally, doctors, again, new to the drug, patients and caregivers new to the drug, are fine seeing their patients in the office for the infusion.

And I think the patients and the families are like, it took us several months to get in to see you, we're happy to see you every 2 weeks. I think once they get more experience, subcu probably comes more in the forefront for induction. It also probably coincides maybe with blood-based biomarkers. So there's a couple of potential tailwinds here where blood-based biomarkers, while they're available today, I think, generally, we're looking for a little better concordance of the data with the PET scan and then scalability and what have you. But if you have -- looking out a bit, blood-based biomarkers, the option of subcutaneous, the pathway has fewer steps and obviously becomes easier, all the while, while physicians hopefully continue to get good experience with LEQEMBI.

So I think it's part of what else we see converging and what gives us a view that things get better as we move further in. Those are some of the points.

Eric Schmidt Analyst

Okay. With the subcu induction, we're still talking about equivalence.

Charles Triano Executive

Yes. That's right. Within a range.

Eric Schmidt Analyst

So within a range, you're either at the higher or lower end of that range.

Charles Triano Executive

That's right.

Eric Schmidt Analyst

You were a higher level, and now you'll be going to -- so it's not going to be dramatically less than that [720] milligram dose.

Charles Triano Executive

Correct. Correct, yes.

Eric Schmidt Analyst

Yes. Okay. Great. So let's shift then to SKYCLARYS. We've seen a good initial launch.

And I guess even in the last couple of quarters, somewhat steady patient-by-patient growth or quarter-by-quarter growth. Maybe just talk about the U.S. and then where are we with the ex U.S. launch as well? Historically, Biogen has said that as much as 2/3 of this market, right, could come ex U.S., I think.

Charles Triano Executive

Yes, that's right. That's right. So yes, we -- I know you and I have spoken about this. I think as we track rare disease launches, you get your bolus. SKYCLARYS had an unusually large bolus just because the bolus was allowed to build for a longer period of time post approval, given there's some manufacturing issues that delayed the actual launch.

So the bolus, you probably got patients who, in a "regular" launch, might not have been in the bolus. So we had really a significant bolus, which is fine. We've got a lot of patients on drug, and then move to a typical rare disease launch where you start to go more patient by patient.

I think with the Street, there was, in our view, some surprise or is this flattening and what have you. Two quarters ago on our earnings call, we actually showed a slide tracking, post launch, how you're looking at these launches of other rare disease launches. And SKYCLARYS, on top. And the shape of the curve, bolus and then a gradual move through that point. So we are now at looking -- and it's really interesting here.

We're using some AI that is going and looking at coding, medical records. We don't have patient names, but we have ZIP codes, physician practice, code of some type of ataxia, may not have been confirmed Friedreich's, and we are going out to those physician practices. And many of these patients haven't seen a doctor for 5 years. Many of them, in fact, are a little bit older and have just been living with this undiagnosed. And we're getting some good hits that way.

So in terms of how do you go find some needles in a haystack, we've got some help with AI, and that has been playing off nicely. But again, it's -- we're talking about 4,500 patients in the adult setting in the U.S. So continued view here.

I think people ask about discontinuation rates. Pretty much the same that we saw in clinical studies. But most of the patients now are with single physician. So centers of excellence, if you look at what we are doing in some of our other rare disease launches where you have more patients at centers of excellence, if you look at SMA, for example, a lot of those -- most of those patients are at centers of excellence. Some with Friedreich's ataxia are there, but there are more dispersed patients.

So we're moving -- we've got an external team that is paid to find these patients, looking at the data. So they get a small fee if they can identify patients.

One example. We found a patient and tested the rest of the family. Since it's genetic, found 5 patients. So you have ups and downs. And some people say, well, what's the number every month you're going to get?

It really depends. We are growing patients every month, but that's why we -- after the initial launch, let's back away from a metric to say, this is how many patients a month, because you

know there's going to be months above and below. And suddenly, that becomes the whole story. And then...

Eric Schmidt Analyst

We just have another minute. But yes, sales heavily weighted to the U.S. right now.

Charles Triano Executive

Europe doing a great job with the launch there. It's of European descent, so we have got France, Germany, in the market. The next big ones coming online, Spain and Italy. So doing very well. Our European team had been clamoring for a new product launch for quite some time, so they are really on the game there.

And we have said that if you look at Europe, maybe close to half of the sales come from Europe. Latin America could be another 10%, so this is really a global story. And we've said pricing is not too dissimilar from what we're seeing at a sort of a Medicaid price in the U.S. So pricing is pretty well established, we think, in Europe and at, I think, a reasonable percentage of what we're getting in the U.S.

Eric Schmidt Analyst

Chuck, we are out of time. Always a pleasure. Thank you very much for being here.

Charles Triano Executive

Always a pleasure. Thank you, Eric. Yes. Thank you, everybody.