BIIB Earnings Call Transcript

Date: 2025-10-30

Quarter: 3

Operator: Good morning. My name is Cynthia, and I will be your conference operator today. At this time, I would like to welcome everyone to the Biogen Third Quarter 2025 Earnings Call and Business Update. [Operator Instructions] Today's conference is being recorded. I'd like to turn the conference over to Mr. Tim Power, Head of Investor Relations. Mr. Power, you may begin your conference.
Tim Power: Thanks, Cynthia, and good morning, everyone. Welcome to Biogen's Third Quarter 2025 Earnings Call. During this call, we make forward-looking statements, which involve risks and uncertainties that may cause actual results to differ materially from our forward-looking statements. We provide a comprehensive list of risk factors in our SEC filings, which I encourage you to review. Our earnings release and other documents related to our results as well as reconciliations between GAAP and non-GAAP results discussed on this call can be found in the Investors section of biogen.com. We've also posted the slides for our webcast -- we posted the slides on our website that will be used during this call. On today's call, I'm joined by our President and Chief Executive Officer, Chris Viehbacher. Dr. Priya Singhal, Head of Development; Alisha Alaimo, our President and Head of North America; and Robin Kramer, our Chief Financial Officer. We'll make some opening comments and then move to Q&A; session and to allow us to get through as many questions as possible, we kindly ask that you limit yourself to just one question. And I'll now turn the call over to Chris.
Christopher Viehbacher: Good morning, everyone. Thank you, Tim. Can I have the first slide, please. So I think we've delivered a very strong third quarter. In particularly, I'm very happy to see our growth on launch products, delivering year-on-year growth of 67% in the third quarter. The launch products again in this quarter, and if I look at this year-to-date as well, more than have offset the MS decline on a year-to-date basis. LEQEMBI continues to show good, strong, sustained sequential global demand growth with sales globally of $121 million. You may recall that we disclosed in the second quarter that we had increased inventory levels in China. And so we had higher Q2 sales and with some offset now in Q3, but when you look at this on a rolling 12-month basis, we're very happy with the progress we're making on LEQEMBI, the approval of the IQLIK subcutaneous injection for maintenance is now approved in the U.S. and it has rolled out and patients are benefiting from that. SKYCLARYS is now available in 34 markets globally. We've got 30% year-over-year revenue growth. That is actually not as high as even the patient growth because we have a number of early access programs in countries, making sure that patients benefit from the product while we negotiate with pricing and governments around the world. And ZURZUVAE, 150% revenue growth year-over-year. This is just an amazing product. One of the most interesting things is I think we are actually changing the perception of postpartum depression. Every day, there are media stories about this terrible condition from others. Jennifer Lawrence is the most recent person to talk about her experience with postpartum depression. So ZURZUVAE is not just a product. I think we are really revolutionizing how people look at this. And that's important, and it's -- but it's also driving a lot of revenue growth for us. If I look at the pipeline, again, very good strong progress. We have litifilimab Phase III studies now are fully enrolled, and both are now expected to read out in the second half of 2026. Now I look at this as not just an acceleration. Lupus is an extremely competitive area. There are a lot of studies ongoing. And one of the things when you look commercially at a new product is, can I recruit patients in clinical trials? Because that's kind of a harbinger of how things are going to work commercially. So we can accelerate, we can accelerate in

a competitive environment that tells me that already physicians are seeing something special about litifilimab, and I'm certainly encouraged by that not just from the fact that we're going to get the data earlier. But as I say, I think it's a good sign for the commercial success longer term of the product. We continue to build out our early-stage pipeline. As we'll see in a minute, we've got, I think, an extremely robust late-stage pipeline. Now it's the time to turn to an earlier stage. We've started a Phase I study for BIIB142. It's an IRAK4 degrader for autoimmune disease. We actually expect to put another 3 to 4 molecules into our early-stage pipeline over the coming 18 months. And then we continue to be active on the BD side. We announced the agreement to acquire Alcyone Therapeutics. This is a very strategic acquisition for us. ASOs continue to be a mode of administration that is necessary to treat a number of diseases. We ourselves have other products such as salanersen, BIIB080, zorevunersen. And so this is a mode of administration that will be much more convenient for patients and we're seeing other companies obviously also developing ASO. So this is really going to be a breakthrough, we believe, for patients who are taking intrathecal injections. And then we have just added the C5aR1 antagonist through our licensing agreement with Vanqua Bio, one of the nice things about immunology drugs is that they tend to offer you an opportunity to create a portfolio in a product. Once -- as you follow these immunological pathways, they can lead to a number of different indications. And the beauty of that is, of course, that once you've been able to demonstrate safety, you can then very efficiently go into other indications. And again, we expect to announce at least another one, if not two, further research stage deals by the end of the year. So if we can move to the next slide, please. Now these are -- I love this slide. When I look at this and I look at the lines that are extending all the way across the page, I mean, a company our size, 10 Phase III or Phase III-ready programs and that covers 5 Phase III NMEs. And we've got a lot of conviction around this pipeline. And we've seen a lot of good data in Phase II. And we're getting close to now seeing a lot of the readouts out of that. Now one of the things that you probably don't think about is that these are not just 10 Phase III programs. This is also 10 launches. If I take just felzartamab as an example, there are 4 indications of that, 2 of those, AMR and MVI are transplant. Two of those are in nephrology. And then, of course, we've got lupus coming along with three indications in lupus. And of course, we're still in rare disease with zorevunersen. We have a next generation of SPINRAZA with salanersen, and we're quite excited about what's coming along with BIIB080 in tau, but all of those require now that we start building up commercial teams building insights, thinking about pricing, thinking about value propositions. So a lot of activity going on inside the company. Another thing I'd like to look at in terms of trying to predict whether things are going to be a success or not is, can we attract strong talent. Because people bet their careers when they come to a company and especially if it's a new product. And I have to say I've been super impressed with the talent that we've been bringing into Biogen. And that sort of says to me that people are willing to bet their careers on these exciting new products. And I have seen time and time again over my career that, that often translates into commercial success. Market research is important, but I think some of these other indicators are even more important. So we go to the next slide. So what we've been trying to do over the last 3 years. The first is, obviously, let's grow our new product launches. And again, 67% revenue growth says this is a very strong performance. We've got LEQEMBI, SKYCLARYS, ZURZUVAE even QALSODY. And when I look over the last trailing 12 months, it's almost $1.2 billion in revenue. So -- and obviously, these products all have long runways in terms of market exclusivity and in each of these, these are first in first -- not only first-in-class, but first-ever treatments in these areas. So we're actually doing an awful lot of market creation, but for those of you who've got a lot of commercial experience, you know that creating markets is a lot tougher than just going into established markets and taking market share. And I think that speaks to a lot of the commercial strength of our teams at Biogen. Then let's look at the profitability of our legacy business. And yes, I think we beat on the top line this quarter because of MS. But that's not all by accident. And I think we are beating just about every analog when you're looking at products that have come to the end of their market exclusivity periods. I think that speaks to the strong customer care. I think it speaks to the strong loyalty of patients to Biogen's product. We are still the company that treats more patients with MS than any other company out there. And one of the things that we shouldn't forget is it's not all legacy. There's an amazing product out there called VUMERITY that has been growing very strongly this year. It's almost $0.5 billion sales in the first 9 months of this year. And this is a product that has market exclusivity well

beyond the end of the decade. And we're proud to see particularly our U.S. team investing more into this business and that is responding well. And it is really the only patent-protected product still in the oral segment, which is extremely important part of the MS market. And then we've been very conscious of being efficient. We are going to deliver this $1 billion of gross savings. We were clear right from the get-go that we would be investing some of that as part of the launch in our new products, but also in research and development. You've seen our revenue growing, but our OpEx growth was still flat over this year. Despite a lot of new investments, we have added products to our late-stage development and we are doing all of this recruitment for the commercial preparation of all these launches that are now in Phase III. And then obviously, if I look at our pipeline, we have cut development costs by almost 25% and research by 40% and I would argue that we have a stronger pipeline than we did before. And that's really a lot of what Priya has done in terms of being very careful about, which products we put into development, building conviction behind those. I think as I look at the pipeline, I'd say we've got a very exciting and a high conviction late-stage pipeline. One of the reasons that we're doing these early-stage deals is, I think we now need to build an early-stage pipeline and Vanqua is just one example of that. We continue to generate strong cash flow, and we continue to look at where are the opportunities across the entire spectrum about how we can grow our business. I think we are very disciplined about where we put that cash flow. Everything that we want to invest in has to be something that contributes to growth. And so with that, perhaps we can learn a little bit more about our pipeline, and I'll pass it over to Priya.

Priya Singhal: Thank you, Chris. This year, we've made important progress across the development pipeline and we are positioned to continue to deliver multiple expected milestones over the next 18 months. As Chris noted, we remain focused on execution against our strategic objectives. And there are a few achievements I'd like to highlight from this quarter. Importantly, as Chris mentioned, despite competitive recruitment for trials in the space, we have now fully enrolled both TOPAZ studies for litifilimab in SLE. This allows us to now pull forward both expected readouts from these studies into next year 2026. Next, we continue to advance two exciting new opportunities. First, with salanersen where the pivotal study design for presymptomatic infants and the broader clinical development plan has been aligned with the FDA. We are also engaging with ex-U.S. regulators and expect to initiate the registrational study in early 2026. We also continue to advance Felzartamab in Late MVI, where we expect to initiate a potential registrational trial in coming months. And today, we announced an update on high-dose SPINRAZA, where the FDA provided us with a path forward. We resubmitted promptly, and now we have a PDUFA in April 2026. Over the last few years, we have transformed both our late-stage and early-stage pipeline. We have followed the science and secured proof-of-concept to advance high-scientific-connection assets into potentially registrational stages. And as we prosecute the early-stage assets, we continue to follow the science by testing the most important scientific hypothesis. We now expect to deliver several readouts from our pre-POC pipeline next year. We're also focused on broadening the pre-POC pipeline, both with internal research assets that we advanced to IND stage like BIIB142 IRAK4 degrader and by also remaining deeply engaged in targeting external innovation, including our announcement last week, as Chris mentioned, to collaborate with Vanqua Bio on a preclinical C5aR1 antagonist. Turning to our late-stage pipeline. I'm encouraged by the breadth of opportunities to further scientifically advance our assets including our ability to educate on the profile of our innovative medicines with our data. For example, this week at ACR we presented important differentiated data from our positive Phase III DAPI trial, showing a consistent clinically meaningful benefit across outcomes that are relevant for SLE patients and providers such as flare reduction, fatigue, morning stiffness, musculoskeletal pain, LLDAS as well as remission. And underscoring our comments that we made at our September lupus seminar on the potential importance of DAPI for patients with SLE, including women of childbearing age we presented data demonstrating limited placental transfer in a preclinical setting. Next, I would like to spend a few minutes on the continued LEQEMBI development to deliver optionality for Alzheimer's disease patients. As you can see on the left side of this slide, we have already been successful this year in delivering meaningful differentiated treatment options for LEQEMBI. Today, it is the only anti-amyloid therapy with a maintenance option as well as an at-home subcutaneous maintenance option. And we continue to advance our rolling submission to the FDA for LEQEMBI subcutaneous initiation. The option for maintenance and the

availability of subcutaneous delivery are also potentially relevant to LEQEMBI in the presymptomatic AD population. The AHEAD 3–45 Study as you can see here, is an important study that aims to comprehensively evaluate LEQEMBI in 2 different stages of presymptomatic AD with the appropriate scientific questions and the relevant primary endpoints. Additionally, we have seen increasing momentum in the development, approval and utilization of blood-based biomarkers. We see this as a key enabler that potentially simplifies the diagnostic pathways. We remain excited and believe the potential for LEQEMBI in the presymptomatic AD population can be an important opportunity for Biogen. In closing, I'm encouraged that LEQEMBI AHEAD 3–45 Study is just one of several important registrational readouts we have over the next few years. As you can see on this slide, our high scientific conviction pipeline will play a critical role given the increasing momentum in our registrational data flow. This will begin with 2 litifilimab Phase III readouts in SLE next year, and 2027 onwards, we will see multiple registrational readouts across several assets in diverse and important therapeutic areas. With that, I would now like to hand the call over to Alisha for an update on our commercial business.

Alisha Alaimo: Thank you, Priya and good morning, everyone. Today, I'll review the commercial results we achieved in Q3, beginning with our multiple sclerosis portfolio. Our MS business continues to deliver significant revenue, which provides the resources to invest in our growth products, advance our pipeline and achieve our vision for the new Biogen. In the U.S., we saw strong performance, mainly driven by strategic actions to support VUMERITY's growth and some onetime events. When we look at competitive dynamics globally, we are seeing increased impact of TECFIDERA generics in Europe. And for TYSABRI, we believe we are well prepared for our biosimilars entrant in the U.S. Now turning to LEQEMBI, which delivered another strong quarter with global revenues growing 82% compared with Q3 2024, underscoring its increasing impact on the Alzheimer's community worldwide. In the U.S., our team is working collaboratively with Eisai driving strong execution and customer engagement, which we believe supported our prescriber base growing another 14% quarter-over-quarter. This quarter, we sustained consistent growth of new writers and new patients and LEQEMBI holds majority share as the #1 prescribed anti-amyloid treatment. Throughout 2025, we estimate LEQEMBI captured roughly half of all the new patients treated with anti-amyloid therapies. Now with the launch of IQLIK subcutaneous auto-injector for maintenance LEQEMBI is the first and only anti-amyloid treatment to offer an at-home injection, giving physicians, patients and care partners more options to continue to slow disease progression following the 18-month initial treatment period. Early feedback from customers and payers has been positive. And into next year, we will remain focused on securing Part D coverage and supporting patient access to LEQEMBI. Last quarter, we noted that for the first time we observed early signals indicating the anti-amyloid market grew with 2 players. We are encouraged that this quarter, our data shows the market continued to grow by approximately 15%. We also shared that blood-based biomarker testing was advancing at a significant pace. And here, our physicians have pointed to a meaningful impact. They report blood tests to help move from probable to definitive diagnosis more quickly, enabling HCPs, patients and their families to focus more on the treatment discussion. We anticipate up to 350,000 Alzheimer's blood tests this year and more than 60,000 PET scans to date, which is a 75% increase compared to this time last year. Our data show early indicators that PET, CSF positive tests are increasing, which we believe may be attributable to increasing use of Alzheimer's blood diagnostics as a triaging tool. As we previously noted, we are educating HCPs about the quality of blood-based biomarkers, including the performance of BBM that meet the requirements of the Alzheimer's Association's new practice guidelines for amyloid triage and confirmation. As we look to 2026, we expect LEQEMBI's momentum will continue to be driven by our focused strategies, which we believe are already having a positive impact on intent to prescribe perceptions of efficacy and safety and health care providers' understanding of the role of anti-amyloid therapies. Moving on to SKYCLARYS, where the launch continues to drive patient growth across all regions, including the U.S. and overseas. SKYCLARYS is now available in 34 countries, contributing to strong growth of 30% compared to the same time last year. In the U.S., as expected, patients continue to grow quarter-over-quarter with quarter 3 revenue being impacted by channel mix in the context of the IRA changes to Medicare. As we shared in the past, our strategy in the U.S. is to reach the remaining Friedreich's ataxia patients, their neurologists and PCPs, which our data indicate are primarily based in the community. Our efforts are focused on delivering on this goal as nearly 2/3 of new patients in Q3

were prescribed by first-time writers and roughly 1/4 of new scripts were written by PCPs. Outside the U.S., we remain focused on continued geographic expansion with multiple commercial launches planned in the first half of 2026. Last, turning to ZURZUVAE, which continues to perform above our expectations. As we shared earlier this year, our expanded field team has had a meaningful impact, delivering $55 million in the U.S., which is a 19% revenue growth compared to last quarter. We are also encouraged by the increasing breadth of writers, which grew 19% quarter-over-quarter. And in quarter 3, 80% of ZURZUVAE prescriptions were written as first line, demonstrating health care providers' belief in the value of therapy that provides rapid relief to mothers impacted by postpartum depression. Across our portfolio, I am proud of our teams for executing with discipline and delivering on our strategic priorities. Their hard work is helping us serve patient communities, build new markets and drive sustainable growth. I will now turn it over to Robin for an update on our financial results.

Robin Kramer: Thank you, Alisha. I would like to provide some key highlights about our strong third quarter financial results. Unless otherwise noted, each of the comparisons I make during my remarks are versus the third quarter of 2024. We delivered 3% revenue growth this quarter, driven by continued strong commercial execution. Our 4 launch products generated $257 million in revenue in the quarter, representing a 67% growth. We continue to see resilient performance from our U.S. MS business which was favorably impacted by gross to net adjustments, timing of shipments and strong demand growth for VUMERITY. This was partially offset by continued generic erosion of TECFIDERA in Europe. Notably, the year-to-date cumulative revenue from our launch products has more than offset the year-to-date decline in our MS product revenue. This commercial execution, combined with our disciplined operating expense management resulted in non-GAAP diluted EPS growth of 18% for the quarter. We also delivered $1.2 billion of free cash flow in the quarter. Turning to our guidance. I'm encouraged by the strong business trends that we continue to observe in Q3. This is reflected in our improved revenue outlook. You'll note that our non-GAAP EPS outlook has been updated to reflect that stronger business outlook while adjusting for expected business development activities that are expected to close in the fourth quarter. I will provide more details on this in a moment. Let me cover some key components of our Q3 revenue performance. Starting with our MS franchise. In addition to the strong commercial execution that Alisha discussed, VUMERITY benefited from approximately $22 million of favorable inventory dynamics. And overall, U.S. MS benefited from favorable gross-to-net adjustments of $38 million in the quarter. Outside of the U.S., sales were primarily impacted by expected generic pressures for TECFIDERA. We continue to defend our IP. However, we observed an acceleration of erosion, particularly in Europe as generics continue to launch in new geographies, including Germany. This, combined with the channel dynamics, resulted in a sequential net decrease in TECFIDERA revenue of $28 million versus the prior quarter in Europe. On a positive note, year-over-year and quarter-over-quarter impact of the TYSABRI IV biosimilar in Europe was roughly offset by growing demand for our subcutaneous formulation, which has no biosimilar alternative and now accounts for more than 50% of all branded and biosimilar natalizumab patients in Europe. For SPINRAZA, we continue to be encouraged by the consistency and demand globally. And as expected, ex-U.S. SPINRAZA was impacted by the drawdown of the inventory build from the first quarter. We continue to expect full year global SPINRAZA revenue to be relatively similar in 2025 as compared to 2024. Turning to our launch products, starting with LEQEMBI. We continue to see steady sequential demand growth globally with third quarter end market sales booked by Eisai of approximately $121 million. As you will recall, we had a $35 million inventory build in China in the prior quarter, representing roughly 6 months in demand in the region. Approximately half of this build was drawn down in Q3. Therefore, as expected, there were negligible sales recognized for China in Q3 as demand was satisfied with the inventory in the channel. We continue to expect demand in China in Q4 to be satisfied with this remaining inventory with minimal revenue generated in the fourth quarter. SKYCLARYS saw continued growth globally with revenue increasing 30% from this time last year. In the U.S., continued sequential patient growth was offset by approximately $6 million adjustment related to channel mix in the context of the IRA redesign related to Medicare. We expect SKYCLARYS to continue to grow, and we are working to secure reimbursement in certain European markets as well as in Latin America. As Alisha noted, we are pleased to see continued strong growth for ZURZUVAE driven by increased demand. Now a few comments on the rest of the P&L.; Before I get into the quarterly dynamics, I would like to

highlight the variance shown here between GAAP and non-GAAP cost of sales. GAAP cost of sales was $674 million, up 6% year-over-year due to an approximately $100 million pretax charge accrued in Q3 that related to a judgment on Genentech's claim for past royalties and interest related to TYSABRI. Without this impact, it would have been approximately $570 million, representing an 11% decrease year-over-year. More broadly, cost of sales benefited from favorable product mix from lower contract manufacturing revenue in Q3 2025, which has a lower margin. This trend is expected to continue through the remainder of the year due to the planned campaign timing of contract manufacturing that we have previously discussed. Non-GAAP core operating expense or R&D; plus SG&A; expense is flat year-over-year. What's evident in our results is that we remain disciplined in our cost management as we continued to deliver on our R&D; prioritization and Fit-for-growth initiative, while ensuring that we are supporting investments in our launch products and long-term growth potential. Now I'd like to provide a brief update on our balance sheet. This quarter, we generated approximately $1.2 billion of free cash flow due to business performance and continued cost management discipline. We exited the quarter with $4 billion in cash and marketable securities, and $2.3 billion of net debt. Our financial strength gives us the flexibility to reinvest in strategic growth initiatives, including advancing our pipeline, supporting product launches and exploring growth opportunities as we work to deliver the new Biogen. Turning now to guidance. We have updated our non-GAAP EPS guidance to reflect a stronger underlying business outlook and investment for growth from business development transactions expected to close in the fourth quarter. As you know, the SEC requires inclusion of acquired IP R&D; charges associated with business development transactions and GAAP and non-GAAP financial results. [indiscernible] onetime charges, our business outlook has continued to strengthen in the quarter, yielding a $0.25 per share improvement. Our updated full year guidance includes an approximately $1.25 per share impact for business development transactions that we expect to close during the fourth quarter including the license agreement with Vanqua Bio and the acquisition of Alcyone Therapeutics. The following are some key considerations underlying our financial guidance. We expect sales to be roughly flat to up 1% as compared to last year at constant currency, an improvement from our last guidance update in July. This reflects strong business performance, including the resilient performance of the U.S. MS business year-to-date. We also expect increased competitive pressures on the ex-U.S. MS business to accelerate, particularly for TECFIDERA in Europe, where we expect the sequential impact in Q4 to be roughly double the erosion we saw this quarter. In addition, as we discussed into July, we are investing to support exciting new pipeline expansion opportunities, including a new program for felzartamab and MVI and the salanersen Phase III study discussed by Priya earlier in the call. As discussed earlier in the call, we are also beginning to invest in prelaunch activities for our late-stage high-conviction pipeline and key initiatives such as direct-to-consumer advertising in support of our launch products. We believe these investments position us to drive future growth while delivering innovative solutions for patients. As we look ahead to the fourth quarter, we expect operating expenses will be approximately $1.1 billion. This reflects the typical seasonality of our Q4 spending, our ongoing investments to drive growth and our focus on cost efficiency. It also reflects the progress we've made in our pipeline with the opportunity to invest in 10 programs, either in Phase III or expected to start Phase III in the coming months. We are encouraged by our progress towards delivering the new Biogen, and we believe it's important to make these investments as we work toward our goal of sustainable growth and long-term value to shareholders. Importantly, we believe we remain on track to deliver the $1 billion of gross savings and $800 million of net savings projected under the Fit-for-Growth initiative by the end of 2025. And as I have mentioned previously, we expect contract manufacturing revenue in Q4 this year to be $10 million to $20 million due to planned timing of contract manufacturing batches versus Biogen innovator product manufacturing. Please be sure to review this slide and our press release for other important guidance assumptions. And with that, I will pass the call back to Tim to open up questions.

Tim Power: Thanks, Robin. Cindy, could we go to our first question, please?

Operator: [Operator Instructions] Your first question comes from Umer Raffat with Evercore.

Umer Raffat: I wanted to spend a quick second on EVOKE trial, if I may. And my question is, in a scenario where we do see a trend, how do you see that impacting the LEQEMBI franchise? And even more importantly, how does that change your thought process around the portfolio offering you have in

the space? Would you need to have a GLP collaboration or an asset in-house in a scenario like that?
Christopher Viehbacher: Well, I think on the study, let's see what the results are and where that's going to affect. We've looked at that. I think if it is positive, we do think it's probably going to be more used in the primary care setting at an earlier stage. We'll have to see what the -- again, what the results are, but it doesn't seem like this would actually affect the amount of plaque I do think, as a company, though, we are interested in having a full portfolio of products to achieve Alzheimer's. We have the BIIB080 program. And obviously, working on brain shuttle technology so I think we would probably evaluate that as and when the data are available. There's certainly no lack of GLP-1s out there.
Priya Singhal: I can just add that I think what's really important here is that they are hypothesizing that neuroinflammation will play an important role. And as Chris mentioned, I think that it doesn't really target the pathology. The important thing is that the EVOKE trials included patients on stable doses of Alzheimer's treatment, including the anti-amyloid antibodies. So we'll be interested in seeing that data. And what we also believe is that it will increase the awareness of the disease and the need for treating disease early.
Operator: Your next question comes from the line of Evan Seigerman with BMO Capital Markets.
Evan Seigerman: Can you step back, I'm really struck by your progress in immunology. Can you just talk to me about how this renewed focus can drive growth and pipeline expansion into the end of the decade? And what can you do with Biogen to accelerate some of these programs?
Christopher Viehbacher: So maybe I'll start. When I came to Biogen, I argued that we've always been in immunology because basically, a lot of diseases like MS, we are treating by really trying to have an impact on the immune system. As I pointed out, our MS drugs don't even cross the blood-brain barrier. So I would argue, we've always been an immunology company. And immunology is really an area that has really flourished over the last 10 years. And I think DUPIXENT was really one of the first drugs to really demonstrate the disease-modifying capability when you follow those pathways, and of course, they can lead into a wide range of activity. So that's an area we understand. In the short run, I think we're more focused on rare immunology and immunology that is overlaps with areas that we already have some experience in. I would argue, for example, with lupus, lupus is an extremely complex disease with a lot of different symptoms and things that affect patients. And I think the experience that Biogen has had in MS will be directly applicable to lupus. And I think we'll be able to develop that market in a way that the existing companies with their products haven't been able to do. And I think over time, we can actually build out a portfolio of products that broadly affect the immunology. There's a lot of opportunity here. There's a lot that we still don't understand. And as we look at kind of the first -- the next 5 years, they're more in this rare immunology. But if I look at a 10-year time frame, then I think we can go into broader indications. And Vanqua is just one example of bringing in an asset that could actually have multiple indications. And I think you'll see us do more of those. And again, these are areas where you really have to have a deep scientific understanding of how these pathways work. They can be -- there are a lot of things that cross over. One of the things that we just see in diseases Nrf2, microglia and things like that actually cross over diseases. And that crossover I think is something that we can bring to the immunology part as we go into different indications even with felzartamab, for example, although we're in 4 kidney indications, we're looking at another 3 indications that have nothing to do with kidney and again, because we understand things like neurofilament and other things, we think that we have perhaps some insight that will allow us to develop medicines that other companies don't. So for us, it's a core area. We're not abandoning neuroscience by any means, and we still have a very strong investment in Alzheimer's and ALS. We still have a big one going on in Parkinson's as well. But I do think immunology is a great space for Biogen to be.
Operator: Your next question comes from the line of Salveen Richter with Goldman Sachs.
Salveen Richter: You mentioned a focus on expanding your early-stage pipeline via BD, and this is partly driven by the late-stage pipeline here where you have about 10 Phase III trials ongoing. Could you just maybe speak to the confidence in the latter that's allowing you to kind of maybe just work on that earlier basket here.
Christopher Viehbacher: I guess there's 2 parts to the question. The confidence in the late-stage pipeline, certainly, if I look at felzartamab, I think we feel that we've seen some pretty compelling data in the Phase II. Obviously, there's always a risk as you go into Phase III. But we've got -- we've seen -- if

you just take AMR, I mean we had an 80% resolution of AMR in patients. On IgAN, we saw that actually even 2 years after the last treatment of a patient that they were still seeing a benefit. So makes us believe that we have a disease-modifying effect in IgAN. So all of those things on felzartamab on BIIB080, obviously, we're doing pioneering work. Nobody has really ever reduced tau to the levels that we expect to be able to do so, and we'll see what the results of those trials -- that trial is. As I look at lupus, again, we had very strong Phase II results, I think, particularly in CLE where there is no drug yet approved. I think we have a very strong belief dapirolizumab has already proven itself in 1 Phase III. And so doing a second Phase III would seem to be -- have a reasonably high probability of success. And I think, again, even on the SLE and litifilimab, it's an area that the company has been working on for quite a long time. So I think there's never a guarantee in research and development, but I think we have morphed the pipeline from a lot of moonshots, if you like, to something where we've actually had a thoughtful progression and derisking of our pipeline. And if I look at the peak sales potential of that late-stage pipeline in relation to our existing business. [Technical Difficulty]

Operator: Ladies and gentlemen, this is the conference operator. We are experiencing an interruption in today's call. Please stand by. I'm going to place music back on the conference. Do not disconnect your lines. Thank you. And you are now reconnected with the audience. You may proceed.

Tim Power: Great. Thanks. Sorry, we got disconnected there. Chris, do you want to just respond to the last question, and if you don't mind?

Christopher Viehbacher: Yes, I'm not sure where we dropped off. It's interesting with all the hundreds of billions of dollars going into data centers and AI. We still have things like telephone calls. Yes, just on the -- so again, high conviction around the late stage, early stage, we are building a lot of commercial capability now in preparing for the launch of that late stage. Building up an awful lot of capability and understanding of immunology and now it makes sense to actually continue that and build upon that in the early stage. A lot of companies get so focused on the launches and the late-stage pipeline that research can sometimes be neglected. But this is now really the time to be investing in the next generation of products. And I would argue there's never been a better time to be in immunology. And I think Biogen is ideally suited to it.

Operator: Your next question comes from the line of Brian Abrahams with RBC Capital Markets.

Brian Abrahams: Maybe a question for Alisha. Can you give us a sense on the early experience with LEQEMBI subcu maintenance uptake and access with regards to non-formulary exceptions what the potential timelines might look like to get on formularies, both for maintenance and induction? And maybe whether we should be thinking about net price here, ultimately landing at parity between the IV and the subcu forms?

Alisha Alaimo: All right. Thank you for the questions. I think so far, the feedback has been very positive from not only payers, but HCPs and patients. We also anticipate that subcu maintenance is going to enable patients to also stay on therapy longer. So we see it as a big upside. It will take some time for providers and patients to just with new outpatient treatment modality even in a maintenance capacity. But we do see this as a great bridge as we move into the potential of subcu initiation. So we do expect a gradual uptake, but over time, it will become a meaningful driver for long-term therapy and for our treatment outcomes. Now and into next year, what the teams are doing is first are educating sites on what you referenced, which is this non-formulary exemption process. However, payers have told us that this should not pose challenges to HCPs who are interested in transitioning their patients from IV and we are already aware of the first patients successfully navigating this process with their physicians, and we do know that we have several patients that are already on subcu. We also have a companion that has rolled out to the entire market that also helped patients with how to do the auto injection, making sure they get their shipments and also making sure that physicians feel comfortable. Also through the non-formulary exemption process, if you look at analogs in the market outside of Alzheimer's disease grade rates are typically quite high. So again, we don't think that will pose a challenge. And then second is working through this Medicare Part D formulary for in the cycle for the goal of gaining access for patients across the nation. So we are now going through that process for Medicare, and we believe that we will have access, full access by 2027. In the meantime, though, they do go through the non-formulary exemption process. But at the end of the day, we are hearing that IQLIK is really just an amazing option for patients and physicians. In fact, just the other day, I was

speaking to a physician who had done his 10,000 infusion of LEQEMBI. And he said some of his patients are very excited they can go on vacation. They can take this with them, and it's now giving them freedom to be able to travel even more than what they do today. So far, so good. Moving into 2026, and we believe the initiation is going to even be a great accelerator for us as well.

Operator: Your next question comes from Paul Matteis with Stifel.

Paul Matteis: There's been a lot of increasing interest in the prevention studies being run by Lilly and you and Eisai. And I guess I wanted to just ask a broader question. How should we think about the commercial implications if these studies are positive? Obviously, these could change the narrative significantly on the utility of Abeta drugs. But what our team is struggling with is it's still a real challenge to actually treat the diagnosed population. There's all these capacity issues. MRIs, it's been a very, very complicated sort of supply chain. And so -- it feels to me like actually diagnosing patients and mobilizing providers to treat people who are asymptomatic might create even more significant capacity issues and difficulties with, again, the whole chain of how to kind of use and monitor these drugs. So what would you say to that? And how can you guys sort of prepare for a successful outcome here to actually generate a significant ROI?

Alisha Alaimo: Thanks for the question. I'll go ahead and take that one. We've been thinking about this quite a bit, obviously, with top of mind as the potential of a successful trial reading out, whether it is going to be Eli Lilly's trial or it will be Eisai/Biogen's trial. And some of the things that we're looking at is especially in the PCP area, how they improve the quality of their referrals into physicians. Now as I said, blood-based biomarkers are growing at a rapid pace. Also just recently, Roche had a BBM that was approved called Elecsys. And this is really only a rule out BBM and is approved for a primary care setting, which basically helps them with this sort of asymptomatic or very early stage, Alzheimer's disease. So we believe through some of the efforts of the field on educating, which, by the way, we're not the only ones. There are several organizations that are supporting these efforts to make sure that physicians understand that a lot of these BBMs meet the criteria for confirmation. And what we're seeing is that during a pilot that we're running now, which we'll read out after the next quarter is can we actually improve the prescribing or the diagnosing and also then the referral and the quality of that referral. I will say, though, that we are seeing already in PET CSF that the positivity rates of those tests have increased dramatically as well at the beginning of this journey, we were sitting at 50-50 positive versus negative and we are now north and upwards of that number and positivity. We believe that's through the improvement of the triaging with the blood-based biomarkers. So I think that's one part of it. The second part of it is, of course, some of these patients then won't land in Medicare depending on their age. And so it's how do we also socialize and work with the commercial plans because they are the ones that would need to cover the product at that point. And so clearly, some of those conversations have already happened because we do have some younger population patients that want to go on product -- and so I do think we are thinking through that. And by the time these trials read out, I do think that capacity will be also much better.

Christopher Viehbacher: And I think we can also say to complement what Alisha just said, the subcutaneous form when that -- if that gets approved as we expect for initiation for maintenance. If the blood-based diagnostics start to replace the PET scan and the lumbar puncture, you're dramatically reducing the workload at the neurology. And as we've talked about in past meetings. A lot of what we've been doing is trying to make the care pathway simpler for physicians with the idea of being able to increase throughput. And as Alisha rightly pointed out, I mean, Today, about half of the patients who are able to get an appointment with their neurologists are not actually eligible. And again, as we increase that yield really from the referrals, as Alisha pointed out, that again will significantly increase the capacity. And we have to say that we still have quite a few neurologists that have not yet actually initiated therapy on Alzheimer's. So this -- I think we'll still -- as this comes along, I think we'll find that the capacity will flex.

Operator: Your next question comes from the line of Marc Goodman with Leerink Partners.

Marc Goodman: My question is about SKYCLARYS. Can you just give us a little more color on what's happening behind the scenes? I mean, you mentioned the $6 million impact in U.S. sales, and you talked about OUS reimbursement issues a little bit. what's going on with volume growth maybe in the U.S. and then just overseas? Or are we seeing patient growth? Are we seeing good persistence like

are there discontinuations? Just give us a sense of just what's happening with SKYCLARYS a little bit more?

Alisha Alaimo: Thank you. I'll go ahead and take that question. I think first, 4, I'll start with ex-U.S. Building on the successful launch in the U.S., we continue unlocking new geographies for SKYCLARYS, which is now available, as we said earlier, in 34 countries. And we are pleased to see the steady and continuous growth once the access is granted overseas. And with that is a country-by-country basis, and they do continue to add patients on a weekly basis, which we see updates about. When you look at the U.S., the U.S. is in a different situation because we did launch earlier. And with that, we have basically had very high penetration in our centers of excellence, and we believe 90% of our remaining opportunity sits in the community. And so we do have patient growth, and we do have volume growth. When it comes to discontinuations, when we first launched, we did notice that in the beginning, our discons, though in line with MOXIe, we're happening quite early on, and we put a lot of tactics into place over this last year to address that with not only the field force, but the medical team. And I will say, fast forward to today, our discons rates have actually declined. So we've improved our discontinuation with education with physicians about some of the side effects they see and also what patients can expect. I think the second part of this, which I think will probably impact the entire world with this launch is how patients after they've been on it for a year or 1.5 years, because it slows the progression, it's very hard to be able to see like what is slowing progression look like. And we have had a couple of instances where patients have discon after about a year's time period, they've declined actually quite quickly, and they've now come back on to products. So we do know that at that time point, we will put more tactics into place on educating the actual patients and activating the patients.

Operator: Your next question comes from the line of Andrew Tsai with Jefferies.

Lin Tsai: So going back to Alzheimer's, you guys have a Phase II tau data set coming up mid-2026. So I'm curious what you would want to see on CDR-SB and the degree of talent reduction as well? And if that study is positive, what would be your guys' base case and upside case expectation on the regulatory pathway?

Priya Singhal: Sure. So I think overall, we believe that tau is really important pathological target and accumulation of tau is relevant and central to Alzheimer's disease. With BIIB080, the approach we've taken is really to address whether knocking down tau, all 6 isoforms of tau can result in target engagement. So we would need to see impact on biomarkers, fluid biomarkers, imaging biomarkers and then see at least a trend on the clinical benefit. That would be important for us to kind of think about the hypothesis. We know that early-stage research in AD is always highly uncertain. But I think if this hypothesis is proven, there's a huge opportunity. Now I think the other question you had was how would we think about it in the portfolio perspective. I think once we have that, it would be a stepwise approach to thinking of if it is positive, is there value to combination, parallel, sequential dosing and these are areas that we're thinking about really deeply as we think about what would be the optimal approach and outcome for patients with early Alzheimer's.

Operator: Your next question comes from the line of Terence Flynn with Morgan Stanley.

Terence Flynn: Maybe just a follow-up for me on tau. I know J&J; is progressing an anti-tau antibody in Phase II and could have some data early next year. You guys obviously explored this approach as well. I think there are some differences maybe in terms of binding here. But when we see that J&J; data, assuming it comes before BIIB080, how should we think about read through to your ASO program.

Priya Singhal: I think overall, based on what I understand from the J&J; program, this is posdinemab. And it's a tau monoclonal antibody it targets the mid-domain of tau. So it is different. And in our experience, we've had an experience and the field has had an experience of targeting tau with monoclonal antibodies thus far, that has not been promising. And we believe that the main reason here is the extracellular tau that it targets. And actually, that is the hypothesis [posdinemab] is testing. So we'll wait to see they are in Phase II. And I think what we saw from the Phase I data was an impact in some of the fluid biomarkers. However, we didn't actually see any data on tau PET, which we believe is very important. So we'll look for that data. And in terms of read-through I think, as I said, it's early days for research in Alzheimer's disease with an anti-tau agent. So we'll have to see what we see and then really try to analyze it, but I think if it works, it could be helpful, right? Because it would then address the

point that is knocking down tau actually has an impact. So I think it would be overall positive, but we wait to see the data first.

Operator: Your next question comes from the line of David Amsellem with Piper Sandler.

David Amsellem: I have ZURZUVAE question. So just wanted to get your thoughts on the fit of the product in the commercial portfolio, given that it's primarily a women's health product that doesn't really synergize with your other business units. I guess, how are you thinking about keeping the asset now that more well-resourced well-capitalized partner now controls the other 50%?

Christopher Viehbacher: Well, I'm not sure how well capitalized I would say. I think we are -- we still feel like first, we are very happy with the partnership with Supernus, I mean that is going extremely well. And they have taken a different approach than Sage, but I do think that this is still a product where Biogen actually can play a significant role. There is a huge unmet need. You're having to shape a market. And that is an area where commercially Biogen is very strong. From a resource point of view, I'm not so sure that even for Supernus is this is an easy fit because the prescriber base for Supernus typically is a psychiatrist, but here, the main prescriber is actually the OB/GYN. And so the resource level, I think, compared to the actual sales and profit of the product, still mean that this is an opportunity. I'm not sure we are keen to get into other neuropsychiatry areas, but I think in terms of being able to create a market, Alisha and her team are doing a terrific job. It was a tricky one because, again, this is a one-and-done treatment. And so you really have to build prescribers who are prescribing multiple times. But the opportunity is significant. There's only about 80,000 women treated today and about 500,000 mothers, and this is just the U.S. alone, I believe this suffer from postpartum depression. So I think this fits very much with the ethos of Biogen. And I don't know, Alisha, whether you want to add anything there?

Alisha Alaimo: Yes. Just to add to what Chris said. I mean, first of all, we have really gotten off to a great start with Supernus, and they've done a really nice job of trying to minimize the business impact anytime you have a handover. And so we really are off to a very good start with them. On the surface, it looks like there are synergies when it comes to the rest of the portfolio, but that's only when you look at really the field force. If you look behind the scenes and you look at really our infrastructure of Biogen, which we're in a very fortunate situation. And you look at things like our bio group, which is really our commercial operations group, we have a lot of synergy when it comes to data and analytics, insights generation. And especially, we have a very strong omnichannel presence. And so what's been great about even putting ZURZUVAE into our portfolio is that we've been able to utilize a lot of the back office support to support this launch. And we believe that's also part of the reason why the launch has been successful is because of all of the experience that we've had with our other products. And also with our AI generation, we're doing some really interesting things for the ZURZUVAE launch as well. So stay tuned also on some more direct-to-consumer that we're planning for next year, which I think is really going to be a great accelerator for ZURZUVAE.

Priya Singhal: Maybe I can just add that we also have approvals in the EU and U.K., and it is a very important moment for mothers with PPD because it wasn't really recognized as an entity, and this speaks to the quality of the data and the efforts and the high unmet way.

Operator: Your next question comes from the line of Jeff Meacham with Citi.

Unknown Analyst: It's Ross on for Jeff. I guess our question is, how was -- how is the company thinking about capital allocation, especially considering balancing BD and new launches, especially if there seems to be a heightened focus on developing an earlier-stage pipeline?

Christopher Viehbacher: Yes. Thanks, Jeff. I mean, first, everything we're doing, as I said earlier, is to invest in long-term sustainable growth. We have been able to, I think, do a great job through previous judgment of building a very strong late-stage development pipeline. I mean a lot of companies when you're putting a lot of things into Phase III development start having to increase the R&D; spend and yet we are still actually spending less than what we did 3 years ago. So I think we've demonstrated capital efficiency on that. We're being very thoughtful, but also the indications. So we're not going into indications where we have to go up against typically an AbbVie or a Sanofi or people like that. So the actual commercial investment is relatively modest compared to the opportunity. And that's, again, a space where Biogen plays well. We are recruiting people to bring in new capabilities in nephrology and in transplant and in lupus, but that's actually a relatively small number of people. And I think one of the

best times to bring in assets is actually pre-IND you can do that on a cost-effective basis. You can take advantage of the fact that a lot of companies have venture capital backed financing, that is designed to take that risk, and you can actually build a portfolio easier of early-stage assets, either by collaboration or licensing and then you bring them in at the right point where Biogen can actually start to use, it's more commercially oriented skills and development skills to shape those products. So I think from a capital allocation point of view, I think we can manage all of this. And I think we still have room, and we're not abandoning looking at later-stage assets, but the later this stage, obviously, the more expensive and you have to be extremely disciplined on ensuring that whatever you buy is going to generate a return on investment. So I think we are in a good spot today. And I think we've got the capital we need to do the business. But of course, we're continually monitoring that and making sure that everything we do is driving shareholder value.

Tim Power: Thanks, Chris. That's it for today. I know it's a very busy morning for everybody. When you've got more questions, the IR team is here to answer those for you. Thank you.

Operator: This concludes today's call. Thank you for your participation. You may now disconnect.