Biogen Inc.

Biogen Inc. - Q2 2024 Earnings Call

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Event Participants

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Analysts 10

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Operator Operator

Good morning. My name is Anna, and I will be your conference operator today. At this time, I would like to welcome everyone to the Biogen Second Quarter 2024 Earnings Call and Business Update. [Operator Instructions] Today's conference is being recorded. Thank you.

I would now like to turn the conference over to Mr. Chuck Triano, Head of Investor Relations. Mr. Triano, you may begin your conference.

Charles Triano Executive

Thank you. Good morning, good afternoon, and welcome to Biogen's Second Quarter 2024 Earnings Call. During this call, we'll make forward-looking statements, which involve risks and uncertainties that may cause actual results to differ materially from those in 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 the reconciliation between GAAP and non-GAAP results discussed on the call can be found in the Investors section at biogen.com.

We have also 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; our Head and President of North America; Alisha Alaimo; Dr. Priya Singhal, Head of Development; Mike McDonnell, Chief Financial Officer; and we'll be introducing Dr. Travis Murdoch from HI-Bio on the call.

We'll make some opening comments, and then we'll move to the Q&A session. And to allow us to get through as many questions as possible we ask that you limit yourself to one question. With that, I'll now turn the call over to Chris.

Christopher Raymond Analyst

Thanks, Chuck. We got a lot to cover this morning. But first, in addition to our regular team of Priya, Alisha and Mike, I'd like to welcome a new member to our team, Dr. Travis Murdoch. Travis is a physician who trained as a gastroenterologist and then studied immunology as a Rhodes scholar at Oxford.

Following a career at McKinsey, Third Rock and SoftBank, he became the Founder and CEO of HI-Bio. I'm pleased to welcome Travis and the HI-Bio team to Biogen. We now have again a presence on the West Coast. And the HI-Bio team working in collaboration with their Biogen colleagues on the East Coast will drive forward the development of felzartamab.

So we're announcing really strong quarterly results this morning, but I would say this is really a quarter that has lasted 18 months. I think we're -- the results we're presenting really reflect the hard work of Team Biogen to transform our company. 18 months ago, we were a company that had been declining for 4 years in revenue and profit. And we have been working pretty tirelessly for the last 18 months to really turn that around and create a new future for ourselves. At the Q4 earnings in February of 2023, we outlined 5 priorities.

The first one was focus on new launches. Second was to reduce our cost base and align resources with growth opportunities. Third was to focus our investments in R&D on the most promising assets and improve the risk-reward profile. Four was to optimize our existing portfolio, and five was external growth.

We've had a few setbacks along the way. But nonetheless, I think the results today really show that Biogen has done what it said it would do. And that, to me, has been always important in business. So if I take each one of those, I think if we look at our new product launches, all of the launches are either in line or ahead of expectations. I'm particularly happy to see the very strong results for LEQEMBI, not only in the U.S., but there's been a very successful launch in Japan.

And the early data from China are also extremely promising, and Alisha will talk more about that.

Last year, we set out to reduce our cost base, and we are more than on track on delivering on those results, and you can see that in the not only in the reduction in OpEx but the very strong improvement in margins, and Mike will talk about that. But one of the things that you don't see in the P&L that I'm particularly proud of is although we've really reduced our cost base and improved our margins, we have invested massively where we need to for growth opportunities, both in LEQEMBI and the other launches, but also on really trying to turbocharge some of the key assets in R&D. And Priya will talk more about that, but one of the beneficiaries of that is BIIB080 and another one is litifilimab. We also have though -- although we have seen a declining MS portfolio due to increased competition, particularly from biosimilars and from generics, we still had a number of products where we still had long patent protection. And one was SPINRAZA.

And I think we've seen some very good performance. This is a very competitive space. And SPINRAZA has been able to hold its own. I think when I first joined the company, most people thought -- were predicting the decline of that.

Today, I would say the bumpiness tends to be in some countries where we only ship every now and then. I think in Russia, for example, we do one shipment per year. So that business has always been a little bit bumpy. But if you look at market share, I think SPINRAZA has done extremely well. And I'm very pleased to see VUMERITY growing at double digits again now in the U.S.

This is the only patent-protected product in the oral segment of MS. And we see an awful lot of movement in the injectable part, but the oral segment has stayed pretty much constant. And it's a great opportunity, and I'm glad to see Alisha and her team really taking advantage of that.

And then we always said we were going to be open to external growth. And I think the Reata transaction last year is really starting to pay dividends. We're seeing a very strong launch not only in the U.S. but now also in Europe. As you know, we tend to get patients on access programs and then the reimbursement follows.

But we are expecting to be approved in 20 countries by the end of this year. And I think we're extremely happy with that. ZURZUVAE addresses a huge unmet need, and that launch is also well in excess of expectations. So as I sit here today, I would say the results that you're seeing are not, as I say, just the results of what we've done in the second quarter. But really, I think we're putting up scores on the scoreboard here that really now are starting to demonstrate all of those initiatives that we put in place last year, and we're starting to deliver on them.

Now of course, we're not done yet. And I think there's a real opportunity to continue to develop a sustainable growth platform and we'll do that in 2 ways. The first is really now that we have prioritized R&D, I see the Alzheimer's portfolio as being a core franchise for us for the coming years. We're obviously continuing to invest heavily in LEQEMBI with the maintenance indication, the subcutaneous. But also, I think the AHEAD study, if we can really get the evidence, that it will really demonstrate the importance of early treatment.

Priya will talk about it, but the 36-month data that we showed at AAIC this week are extremely important for the future growth of LEQEMBI. But we've always known there'll be other modalities. And I think tau is emerging as an extremely important modality for the treatment of Alzheimer's. And I think Biogen is a clear leader in that. And again, Priya will say more about that.

We're also seeing an emerging lupus portfolio. We'll have a readout later this year with dapirolizumab that we share with UCB. But we're quite excited about litifilimab, both for SLE as well as cutaneous lupus.

And we add another element to the lupus portfolio with felza because that is actually in Phase I for lupus nephritis. And to me, and Travis will go into this more, but the acquisition of HI-Bio is extremely important for our longer-term growth outlook. This is an opportunity to present a set of opportunities that have a different risk-benefit profile. We have very strong Phase II results, which gives us a whole lot more confidence in Phase III results than some of the other assets that we have in our portfolio.

Neuroscience is in an area of a very important unmet need, but it's also one of the riskiest and hardest areas. And so I think we get a little bit more balance in our portfolio by pursuing

things in immunology, and so I personally am extremely excited about felza and what Travis and his team can do.

The other access to this is we're going to continue to look at business development. I think you have seen that we're pretty disciplined. I think that both of the acquisitions that we've done so far with Reata and HI-Bio will drive an awful lot of shareholder value. And that is certainly top of mind as we look at business development.

So I think Biogen is in a much different place than we were 18 months ago. We still have a number of challenges like any other company, but I think we're really positioned for longer-term growth now at the company.

And with that, I'd like to turn it over to Alisha to give us a little more color on the successful launches.

Alisha Alaimo Executive

Thank you, Chris, and good morning, everyone. Thank you for joining the call today. Today, I'll provide our perspective on the progress of LEQEMBI, SKYCLARYS and ZURZUVAE.

So I will begin with the Alzheimer's market. We believe we're continuing to build momentum with more health systems across the country now having the capability to treat a higher volume of Alzheimer's patients. And in Q2, we saw these promising trends continue. Notably, we sustained new patient growth. Nearly 40% of all commercial patients on therapy since launch started treatment during Q2.

The number of physicians prescribing LEQEMBI also grew by 50%. Depth of ordering at our Priority 100 IDNs continued to accelerate, and the total order volume more than doubled again in Q2 compared to Q1. It's important to know that based on the data we've seen to date, these trends continued into the first weeks of July, demonstrating that we are sustaining launch progress. We also believe we're seeing positive signals that health system capacity may be increasing. For example, last quarter, I described how some IDNS are expanding and extending their sites of care.

Through Q2, nearly 70% of the activated Priority 100 IDNs expanded beyond their flagship sites to treat patients at their trial sites. And we have seen this dynamic play out beyond the priority IDNs as well.

We believe this growing real-world experience with LEQEMBI's efficacy and safety further strengthens its unique profile in a newly competitive market. Specifically, some HCPs share that because LEQEMBI was studied in the broadest and most diverse population of any anti-amyloid drug to date, it removes some of the complex considerations about which potential patients are appropriate for Alzheimer's treatments. Alzheimer's is a chronic, degenerative and fatal disease that does not stop even after plaque is removed.

In fact, our long-term data show that patients who stopped LEQEMBI treatment experienced rapid re-accumulation of key plasma biomarkers that indicate Alzheimer's disease biology was returning. Importantly, the rate of decline in most patients who stopped therapy reverted to the rate of decline observed in patients who took placebo, which is why we believe

patients deserve a therapy with a benefit-risk profile that enables them to remain on treatment to stay ahead of disease progression, even after removing plaques by preventing ongoing damage and plaque buildup.

Recent data that Priya will describe reinforces that in patients with 3 years of continuous treatment, LEQEMBI showed continued benefits. And finally, though there are no head-to-head studies comparing the available therapies, the FDA has been clear that the incidence and timing of ARIA vary among drugs in this class. Observed ARIA rates in patients who received LEQEMBI were the lowest reported among any Phase III trial for a drug with traditional FDA approval in the class, with LEQEMBI rates nearly 50% lower.

To reinforce LEQEMBI's unique profile with our customers, Biogen deployed our expanded field force just last month. This team increases our focus and frequency, engaging with high-value sites and expands our reach to 30% more HCPs. We've been receiving positive feedback since the launch of this team. Biogen's field force is working even more closely with our partner, Eisai, and we believe this is deepening our customer insights, and we will enable accelerated growth. We're encouraged by 2 strong quarters of growth and the sustained progress in July, and we look forward to providing more support to the healthcare community and people living with Alzheimer's disease.

Now moving on to the SKYCLARYS update, where we continue our strong launch momentum, reaching more Friedreich's ataxia patients globally. In the second quarter, we delivered $100 million in revenue globally and remain ahead of our internal expectations. Europe launch is ahead of internal forecast and along with rest of world builds on the success in the U.S. SKYCLARYS is now available in 12 markets outside the U.S., including the EU, where we are initiating new patients in the catch-up population. These patients and their HCPs are highly engaged in their care and often awaiting SKYCLARYS approval, as is typical for rare disease launches.

In the U.S., we have moved beyond the catch-up population as SKYCLARYS has been in market for more than a year. The team continues to leverage our strong rare disease capabilities, and we are encouraged by the early results of engaging patients and physicians in this next phase. In Q2, roughly 1/3 of new patient start forms came from new riders tied to our AI program, which analyzes hundreds of thousands of de-identified patient journeys. This includes a meaningful share from community neurologists and PCPs. Globally, our outlook in FA is promising in both the short and the long term.

We anticipate driving strong growth by making SKYCLARYS available in additional geographies, potential expansion into pediatric populations. And with our years of experience identifying patients, we believe we can help.

Turning to ZURZUVAE. We continue to outperform our expectations in the first 6 months of launch. We saw strong growth in the second quarter with U.S. revenue growing 19% and patient demand nearly doubling versus the first quarter. OB-GYNs continue to lead prescribing, and patients are sharing positive early experiences with their physicians and on social media platforms.

Based on our recent market research, we believe we've achieved higher-than-average aided

awareness of ZURZUVAE among providers, outperforming messaging recall analogs in the women's health and psychiatry markets.

To achieve the next phase of growth and advance our vision to transform the care of postpartum depression, we are working to more deeply understand how to realize the patient opportunity in this market and drive real behavior change.

In conclusion, while each launch is unique, we are pleased that we remain on track or ahead of our expectations across all 3 therapies. We know we have more work to do to help people living with Alzheimer's, Friedreich's ataxia and postpartum depression, and we are working with urgency to help these patient communities.

I will now pass to Priya.

Priya Singhal Executive

Thank you, Alisha. Over the last year, we have focused heavily on reviewing our existing pipeline with an eye toward improving its risk profile. The focus now is on building the pipeline through a combination of both internal and external opportunities with an eye towards risk diversification and creating value. We also remain focused on investing to win in Alzheimer's disease, where we believe we have a differentiated product in LEQEMBI as well as an industry-leading R&D pipeline of potential next-generation therapies.

Beginning with LEQEMBI. LEQEMBI is the only approved anti-amyloid antibody with, first, a dual mechanism of action, targeting both amyloid plaques and highly toxic protofibrils; second, clinical data across the full early Alzheimer's disease population, including individuals with no and low tau; and third, extensive real-world evidence. Importantly, as Alisha mentioned, Alzheimer's disease is a chronic progressive disease, and we believe the dual action of LEQEMBI and the option for continued treatment is a unique advantage for patients looking to maintain or further clinical benefit.

To this point, at AAIC earlier this week, Eisai presented 3-year data from the Phase III Clarity study and its open-label extension, which shows continued clinical benefit with longer-duration LEQEMBI treatment. Shown on the left, this includes data from the early start group or individuals who started LEQEMBI during the 18-month placebo-controlled portion of the study. Delayed start group or patients from the placebo arm who switched over to LEQEMBI at the start of the open-label extension as well as a baseline-matched natural history cohort from ADNI. The early start group shows that 3 years of continuous LEQEMBI treatment reduced clinical decline by negative 0.95 on CDR-Sum of Boxes as compared to the natural history cohort, resulting in a clinically meaningful benefit for early AD patients. This represents an expansion of the benefit observed at 18 months.

It is very important to keep in mind that a change from 0.5 to 1 on the CDR score domains of memory, community affairs, home and hobbies is the difference between slight impairment and loss of independence. We believe these results are significant as the majority of individuals, approximately 70%, had already successfully cleared plaque by the 18-month time point.

Furthermore, data from the lecanemab Phase II study, shown on the right, which included a

treatment gap of approximately 2 years on average, shows that Alzheimer's disease continues to progress when treatment is stopped or interrupted even after plaques are removed. Also at AAIC, Eisai presented data which showed that 51% of patients in the Clarity AD study with either no or low tau, representing an early stage of Alzheimer's, showed improvement from baseline in cognition and function over a 3-year period as assessed by CDR-Sum of Boxes.

Taken together, these data suggest that earlier initiation of treatment with lecanemab may have a significant positive impact on disease progression and may provide continued benefits to patients with early Alzheimer's disease over the long term. We continue to focus our efforts on LEQEMBI with a goal of characterizing dosing for its long-term benefit, providing optionality with subcutaneous formulation as well as evaluating its role in preclinical AD population, as Chris mentioned.

Lastly, while we were disappointed to learn that lecanemab received a negative opinion from the CHMP, we believe that the clinical data supports a clear favorable benefit-risk profile with a meaningful clinical benefit to patients.

Furthermore, thousands of patients have now been treated with lecanemab globally, providing further real-world evidence on the efficacy and manageable safety profile. We are continuing to work with Eisai as they plan to request a reexamination of the EU filing as we work to enable access for people suffering from Alzheimer's globally.

We continue to also invest in our broader Alzheimer's pipeline, including our investigational anti-tau ASO BIIB080. Based on the encouraging data from the Phase Ib study, we have now implemented a protocol amendment for the ongoing Phase II CELIA study with the aim of accelerating a potential proof-of-concept outcome. We are excited that this amendment, combined with the robust enrollment trends observed to date, may enable a readout in 2026.

Beyond amyloid and tau and under Jane's guidance in research, we are advancing a preclinical AD pipeline that encompasses diverse targets and modalities, including active transport approaches. As communicated today in our earnings release, we decided to exit the ATV:A beta collaboration with Denali.

We continue to see merit in modalities that can actively transport therapeutic agents into the brain, and we continue to prioritize these efforts as we work to build upon our existing leadership in AD.

Looking back over the last few months, while we discontinued 3 mid-stage programs based on readouts, we continue to make progress across several other areas of our pipeline. The first patient has received a dose of SKYCLARYS in Biogen's Phase I dose-finding study for pediatric Friedreich's ataxia. This is the first step in potentially expanding SKYCLARYS access to the pediatric population. And once a dose is identified, we plan to conduct a Phase III study to assess the benefit risk in pediatric patients.

We also expect the DEVOTE study evaluating high-dose SPINRAZA to read out in this second half of the year. We have also made meaningful progress in immunology, where the first patient was dosed in the litifilimab Phase III portion of the operationally seamless Phase II/III AMETHYST study in CLE following the completion of the Phase II enrollment. As Chris

mentioned, we continue to view immunology as a significant potential driver of Biogen's future growth, and the recent acquisition of HI-Bio is an example of this importance.

With that, I would like to hand over the call to Travis who will dive a bit deeper into felzartamab.

Travis Murdoch Executive

Thank you, Priya. I'm very excited to be here speaking today as part of the Biogen team. I believe we have a unique opportunity to combine HI-Bio's expertise in immune-mediated indications with Biogen's global development and commercial experience in specialized immunology and rare diseases. I believe this synergy will have significant benefit as we work to accelerate our lead asset, felzartamab or felza, into late-stage development. As an anti-CD38 antibody, we believe felzartamab has a differentiated molecular design that specifically target and depletes plasma cells responsible for producing pathogenic antibodies, while sparing the broader B cell lineage.

This is different from other programs currently in development for antibody-mediated diseases that more broadly impact B cells. Compared to other mechanisms, we believe the specificity of felza's MOA will allow for a differentiated and more desirable clinical profile characterized by more durable efficacy and improved safety profile.

As Chris mentioned, one of Biogen's goals is to optimize the risk reward of the pipeline, and I believe the acquisition of felza significantly advances that effort. Through a cell depletion approach, felza has already demonstrated clinical proof-of-concept across multiple rare immunology indications.

Antibody-mediated rejection, AMR; IgA nephropathy, IgAN; and primary membranous nephropathy, or PMN, are serious conditions that lead to severe consequences for patients, such as transplant failure or end-stage kidney disease. And available treatment options leaves significant unmet need, and so we see significant potential commercial opportunity here.

Now I'd like to briefly review the felza data generated to date across these indications to highlight the potential value we see for patients. AMR is the leading cause of kidney transplant loss in the U.S. with no approved treatments. And prior investigational agents have not demonstrated significant resolution of AMR biopsy. The consequences here can be dire, ending with graft failure or dialysis and the need for re-transplantation in many cases.

In the Phase II study, which we published in the New England Journal of Medicine, 9 doses of felza IV administered over a 5-month period resulted in greater than 80% AMR resolution at week 24 versus 20% for the placebo group. Furthermore, 2/3 of responders maintained AMR resolution out to 52 weeks. So we believe these results, if replicated in a registrational study, are potentially transformative for this disease.

Next, I'd like to discuss IgA nephropathy or IgAN, which is the most prevalent chronic glomerular disease worldwide and another indication where we believe felza has the potential to deliver a treatment option for patients with important differentiation. Felza directly depletes CD38-positive plasma cells, the producers of both galactose-deficient IgA1 and its autoantibody, which are believed to be the most upstream causes of IgAN.

As shown here on the slide, felza treatment resulted in durable reductions in IgA up to 24 months, which is more than 18 months after the last dose. Importantly, this pharmacodynamic effect was selective for IgA, with IgG and IgM levels rebounding to baseline after the completion of the 5-month felza treatment. These results, paired with the emerging clinical efficacy data, suggest that felza can have a durable selective effect on IgA and thus impact IgAN disease biology, while potentially allowing for the maintenance of general protective immunity conferred by IgG and IgM antibodies over a prolonged period off therapy. Similar to the effects we saw in IgA, interim results from the Phase II IGNAZ study showed a durable reduction in proteinuria as measured by UPCR. Specifically, we saw there was a dose-dependent reduction in UPCR, durable out to the 24-month time point.

Now in terms of potential differentiation, it's important to note that this improvement is after more than 18 months of being off therapy, supporting the potential for felza to be the first non-chronic treatment option in IgAN. Furthermore, in line with the selective targeting of plasma cells, administration of felza was generally well tolerated with a safety profile consistent with prior studies.

We believe these interim results potentially provide for a wide therapeutic window and may ultimately lower the risk of chronic immunosuppression, which could be a significant benefit for IgAN patients.

Moving to PMN. So this is a severe antibody-mediated disease of the kidney that's a leading cause of nephrotic syndrome, which is a severe syndrome resulting from excretion of too much protein in the urine and which causes symptoms such as swelling, fatigue and increased risk of infection. Current standard of care, which includes immunosuppressive and chemotherapeutic agents, has proven insufficient as up to 40% of patients do not achieve remission. And many progress to end-stage kidney disease.

It's estimated that up to 80% of patients with PMN have autoantibodies against PLA2R, which is a kidney antigen and which provides us with a key biomarker, both for patient stratification as well as treatment response. In the Phase II M-PLACE study, which evaluated felza in both newly diagnosed and relapsed patients as well as patients refractory to immunosuppressive therapies, a 24-week felza treatment resulted in rapid, deep and durable reduction in anti-PLA2R antibodies in both patient cohorts at the 1-year time point.

Many patients retained immunologic complete response more than 6 months after the last dose of felza, which highlights the durability of felza's treatment effect. Importantly, the effect on anti-PLA2R was mirrored when examining reductions in proteinuria. And in line with prior studies of felza, TEAEs were generally mild or moderate in severity. Based on these results, we believe that felza has the potential to provide a meaningful new treatment for patients suffering with PMN.

In summary, we believe the data generated to date highlights the potential for felza to be a best-in-class treatment option across multiple serious immunologic diseases with significant unmet need. Phase II data across AMR, IgAN and PMN have provided proof-of-concept and highlighted a potentially differentiated clinical profile on the basis of efficacy, treatment durability and safety. I'm looking forward now to combining the strengths of the joint HI-Bio and Biogen team as we work to incorporate these learnings and further refine our Phase III

plan. Now we expect to initiate Phase III studies across AMR, IgAN and PMN next year, beginning with AMR in the first half of the year.

I'd now like to pass the call over to Mike for a financial update.

Michael McDonnell Executive

Thank you, Travis, and good morning, good afternoon to everyone. I'd like to start by acknowledging the entire Biogen team for a strong second quarter. I'm pleased to provide some color on the results, and please note that all the comparisons that I will make are versus the second quarter of 2023.

Total revenue of $2.5 billion was up marginally versus the prior year at actual currency and grew 1% at constant currency. But importantly, we grew our core pharmaceutical revenue 5% at actual currency and 6% at constant currency. This was driven by the performance of our 4 recent launches, which more than offset the revenue decline in our MS business.

Non-GAAP diluted EPS grew 31% to $5.28 and included a onetime benefit of $0.52 from the sale of one of our 2 priority review vouchers. Absent the PRV sale, non-GAAP EPS would have grown 18% to $4.76. We also reported a 43% improvement in non-GAAP operating income, which was a 30% improvement, excluding the PRV sale. We continue to benefit from our R&D prioritization and Fit for Growth initiatives, where I'll provide more detail in a moment. We are pleased to be raising our full year 2024 guidance range.

And in just a few moments, I will also provide some additional details on our guidance.

Now a bit more color on our revenue for the second quarter. Our MS franchise revenue declined approximately 5% in the quarter, and there are a few dynamics in this business that are worth highlighting. First, we continue to see erosion of our interferon business as the entire class is seeing a shift to higher efficacy or oral therapies. Regarding TECFIDERA in the EU, we have now seen most generics exit the market, which helped drive ex U.S. growth of 11% at actual currency and 12% at constant currency to $208 million this quarter.

We continue to believe that we are entitled to market protection in the EU until February of 2025.

VUMERITY had its best quarter since launch as global revenue grew 13% at actual and constant currency to $166 million. VUMERITY remains the #1 branded oral in terms of share in the United States. U.S. TYSABRI revenue of $249 million declined 4% and benefited from the timing of shipments in the quarter, which was offset by declines due to competition within the high-efficacy class.

Next, our rare disease franchise produced revenue of $534 million and that represented growth of 22% at actual currency and 25% at constant currency. SKYCLARYS global revenue was $100 million. Global SPINRAZA revenue of $429 million declined 2% at actual currency and was flat at constant currency. U.S. revenue was up 1% to $157 million and we remain encouraged by the resilience here.

And on LEQEMBI, we saw significant sequential growth with second quarter global in-market sales booked by Eisai of approximately $40 million, which included $30 million of U.S. in-

market sales.

I'll turn now to a few comments on expenses. We continue to see lower non-GAAP cost of sales as a percentage of revenue, which was driven by a more favorable product mix. Notably, growth in SKYCLARYS replacing lower-margin contract manufacturing revenue. We also had no idle capacity charges during the quarter versus $34 million in the second quarter of 2023.

As mentioned previously, our R&D prioritization and Fit for Growth programs have begun to significantly improve our profitability. Second quarter non-GAAP R&D expense decreased from the second quarter of 2023 by $120 million or 21% as we continue to focus our spend on programs with the highest probability of success.

Non-GAAP SG&A expense increased 1% in the second quarter. We have significantly reduced selling costs for legacy products and also significantly reduced our general and administrative cost base, which has allowed us to absorb most of the approximately $100 million of Q2 2024 incremental launch costs for LEQEMBI and SKYCLARYS.

Now a brief update on our balance sheet. We ended the second quarter with $1.9 billion of cash and marketable securities. As a reminder, we utilized $1.15 billion of this balance in July when we closed the HI-Bio acquisition. We ended the quarter with approximately $4.4 billion of net debt. During the quarter, we fully repaid the remaining balance of the $1 billion term loan that we put in place at the time of the Reata acquisition.

And we continued to generate strong cash flow in the second quarter with approximately $592 million of free cash flow, which brings us to approximately $1.1 billion of free cash flow in the first half of 2024. We continue to believe that our balance sheet has the capacity for us to invest in both internal and external growth opportunities.

Turning now to guidance. We're pleased that the operating performance of the business year-to-date supports raising our full year 2024 non-GAAP diluted EPS guidance from a previous range of $15 to $16 to a new range of between $15.75 to $16.25. This new range reflects expected growth of approximately 9% at the midpoint of the range compared to the full year of 2023.

I would like to highlight several important things to remember for the second half of 2024 as you update your models. In terms of revenue, with our key products all performing generally in line or slightly ahead of expectations, there is a slight increase to the previous expectations for the year. We now expect full year total revenue to decline by a low single-digit percentage when compared to 2023. We also expect core pharmaceutical revenue to be roughly flat year-over-year as recent launches are expected to progress and provide an offset to some key potential dynamics in the second half of the year. These include expected continued pressure on our MS franchise, which incorporates the potential for a biosimilar entrant in the U.S.

for TYSABRI. And we continue to monitor the timing of shipments for SPINRAZA in certain ex U.S. markets.

Next, the sale of one of our 2 priority review vouchers is a nonrecurring item. And since we expect to reinvest the proceeds of the sale in growth initiatives later this year, we do not

expect this benefit to impact our full year EPS. Also, some key points to consider regarding our operating expenses. In the second half of the year, we expect to continue to ramp launch spending on our new product launches. This will include the 30% increase in the LEQEMBI field force, which is coming online, as well as additional spend for some targeted direct-to-consumer campaigns.

In addition, we expect incremental OpEx primarily on the R&D line of approximately $50 million in the back half of the year related to HI-Bio as we execute plans on 3 potential Phase III starts.

We continue to expect full year 2024 combined non-GAAP R&D and SG&A expense of approximately $4.3 billion. We reported approximately $2 billion of spend in the first half of the year, implying higher spend in the second half of the year due to the reasons I just mentioned, along with some typical phasing of expenses throughout the year.

I would also note that we now expect 2024 operating income to grow at a mid-to-high teen percentage versus the previous guide of a low double-digit percent growth. This improvement factors in higher expenses in the second half of the year versus the first half of the year, partially offset by higher revenue due to our new product launches.

I would remind you that we expect a reduction in interest income of approximately $20 million for the remainder of 2024, and this is due to lower cash balances and associated lower interest income resulting from the HI-Bio acquisition.

As always, our guidance does not consider the impact from any potential acquisitions or large business development transactions or pending and future litigations, as these are often difficult to predict. I would refer to you to our press release for other important guidance assumptions.

And just before we open it up for Q&A, I wanted to provide a brief update regarding the strategic review of our biosimilars business. After a comprehensive review of potential externalization options compared to retaining the business, we believe that the best value for shareholders going forward is to retain the business within our portfolio and to optimize the business with an aim to maximize profitability.

And with that, we will open up the call for questions.

Charles Triano Executive

Thanks, Mike. Operator, can we please poll for questions?

Operator Operator

[Operator Instructions] Your first question comes from the line of Salveen Richter with Goldman Sachs.

Salveen Richter Analyst

Congratulations on the quarter. At a high level, there's been significant focus on 2024 as a turning point for the company, both product-wise for the launches and operationally given the cost savings programs and pipeline prioritization. Just given the raised guidance here of

9% year-over-year EPS growth for this year, can you just speak to your confidence around 2023 being the trough year for earnings? And what needs to play out from here for clean growth through the end of the decade?

Michael McDonnell Executive

Yes. Thank you for the question, Salveen. And our mission at Biogen remains to bring ourselves to sustainable growth on both the top line and the bottom line. Obviously, our original guidance, which implied growth of 5% on the bottom line at the midpoint and now 9% at the midpoint, shows that we've now turned the corner on the bottom line. And we're very focused on our cost savings program, which importantly not only improve our operating performance, but also free up capital for growth initiatives.

So that's really important. Obviously, we don't guide beyond 2024. But I would say that when you look at our guidance this year, we're pleased with the fact that we've been able to get our top line somewhat much more stabilized, and we've got the bottom line growing again as we look to next year.

We're pleased with the progress of the launches. Our ability to restore the top line is going to be somewhat dependent on how those launches continue to perform along with how the MS franchise continues to sustain and be durable. And what I can say is that we're very focused on bringing the company back to growth, and we're certainly hopeful that 2023 was the trough year. And obviously, we're doing a nice job growing the bottom line in 2024. And we'll have more to say about the out years as we move to the latter part of this year and into early next.

Operator Operator

Next question will come from Mohit Bansal with Wells Fargo.

Unknown Analyst Analyst

This is [Satya] on for Mohit. I had a question on the EMA decision on LEQEMBI. Do you plan to submit additional evidence on efficacy or safety from trials or from real-world evidence to reverse this decision? And what's your confidence that the decision can be reversed? And what should we think about for a time line for the EMA to reconsider?

And would a [SAG-N] need to be convened for this process?

Priya Singhal Executive

This is Priya Singhal. We are very disappointed along with Eisai at the outcome of the negative opinion for LEQEMBI. We continue to believe that the benefit risk is positive and favorable. As you know, it's been approved in major regions of the world like the United States, China, Japan. And recently, we've also communicated approvals in Hong Kong, Israel as well as South Korea.

So yes, we have communicated publicly, and I can reaffirm that we will be applying for a reexamination process. The way the reexamination process works is that you can continue to work with a newly appointed rapporteur and co-rapporteur for the process. So right now, we

would wait to receive the assessment report from the CHMP. The new rapporteur and co-rapporteur would be appointed, and then we would work with them to understand what are the issues that are driving the decision. And currently, based on the opinion that was rendered, we believe these are addressable with the data that we've generated.

Specifically, we have generated long-term data, as we shared at AAIC. And we would look to be engaging with the EMA and CHMP to see how we can submit additional data and the extensive real-world data that we have in the real world because thousands of patients now have been treated. So we have long-term continued benefit as we showed in the 3-month -- 3-year data at AAIC and also long-term safety.

So we're continuing to work very closely with Eisai on the reexamination process and strategy. It is possible that a new [SAG-N] would be appointed, and this process would generally move faster than the original application.

Operator Operator

Next will be from Kevin (sic) [Evan] Seigerman with BMO Capital Markets.

Evan Seigerman Analyst

It's Evan Seigerman. Question for Priya. Can you walk me through some of the rationale on opting out of the Angelman syndrome program with Ionis? How has your approach to evaluating partnerships evolved recently? And what aspects of a program do you now more closely scrutinize when you're thinking about what to do with a partner?

Priya Singhal Executive

I think just stepping back, I want to point us to comments we've made externally before as well that we have really -- we really looked at our readouts as important inflection points, which allow us to double down, accelerating those programs, if the data are objectively clear and compelling. And then the other option would be that we can pivot and pivot to other programs that we may be considering. So overall, our process is that we develop up a priori go/no-go criteria. And based on that, we decide what the probability of technical and regulatory success is in a particular program. And that is exactly the approach that we applied with the Angelman syndrome, the BIIB121 data.

That is going to be continuing to be the way that we look at all our readouts, and we try to be very disciplined.

I think things that we find very compelling are biomarkers, established regulatory pathways, clinical tractability as well as our confidence in regulatory endpoints or on our -- based on interactions with regulators. So we look at all of these, and that's how we think about investment in Phase III.

Christopher Viehbacher Executive

If I could just add, I think with -- in addition to what Priya said, we're also looking at the ability to launch products globally. And so we also are interested in the level of evidence and regulatory end points as they may be acceptable to payers and regulators around the world

and not just in the U.S.

Operator Operator

The next question will come from Michael DiFiore with Evercore ISI.

Michael DiFiore Analyst

Congrats on the quarter. So I was wondering if there's any updates on the subcu induction dose optimization work you're doing and whether this could lead to a more optimal risk-benefit ratio that the EMA is looking for?

Priya Singhal Executive

Yes. So overall, as Eisai and Biogen have communicated, we continue to -- we've already filed for the IV maintenance, and we have a fast track and a rolling submission in place for the subcutaneous maintenance dosing. With the initiation of subcutaneous dosing, we are looking at optimizing the dose. We're continuing to work with FDA on this effort. And currently, we are on track, as we've communicated, to have an outcome on this from the FDA in the U.S.

by Q1 -- calendar year Q1 2026. Now with regards to your specific question about how this could impact the application in Europe, I just want to be really clear that the application in Europe that currently we're going to pursue, reexamination is dependent on the original application, which is really for intravenous LEQEMBI. We would hope that we can get that -- a favorable outcome at the end of the reexamination process. And if so, we would continue down the path of, again, providing options to patients as well as in Europe with the subcutaneous formulation.

Operator Operator

Next question will be from Chris Raymond with Piper Sandler.

Nicole Gabreski Analyst

This is Nicole Gabreski on for Chris. Maybe just one on LEQEMBI. So some of our survey work we've done recently with neurologists and Alzheimer's specialists has kind of indicated maybe a less favorable view of the risk-benefit and cost-benefit ratios for LEQEMBI in recent quarters. And I guess we're starting to see some feedback from docs also questioning the amyloid hypothesis as a whole. I guess, maybe just given this, could you speak to the interactions and/or feedback that reps are having in the field?

I guess are you starting to maybe experience any pushback as you move from HCPs who are sort of ready and waiting to prescribe LEQEMBI soon after approval to those who are in the next wave of uptake?

Alisha Alaimo Executive

This is Alisha. Whenever we look at market research, I think it's important to understand who you're asking in the market research. And so when we look at what's happening in the field, at least on the ground, when you're asking the physicians, if you were to parse out market

research and ask the physicians who are currently obviously prescribing and the ones who aren't, the ones who are prescribing are the ones that we've been working really hard on over this past year. They're the ones that understand the data. They've been visited by MSLs.

They've been visited by representatives. And then it takes them time to obviously get up and running with their facility.

You also then see across the board that other physicians see this happening and some in like a nearer location will also start obviously picking up the product. And so on the ground and with our representatives, they go from office to office. We're obviously expanding now as well with the additional field force. And what we've seen is the ones that you call on are the ones that actually start writing. And there's a lot of dynamics at play here.

I think that understanding this data is important. I think understanding all the mechanics in order to get a patient diagnosed is important, and having them set up their capacity is important.

And so we don't really hear any pushback about cost benefit. I can say that. And I think more importantly, what we're hearing now is because we are a year out, we're starting to really get the real-world experience feedback from physicians on the impact this is having on patients and the caregivers and the families. And I think that alone has really also accelerated some of these physicians to try and treat patients even more quickly. And so for now, we're not really hearing that pushback.

Christopher Viehbacher Executive

And if I could just add to that, after decades of this, I tend to pay more attention to what physicians do versus what they say. And this is a very heavy lift for physicians to introduce this treatment into their practices and institutions. And when you look at the number of -- the increase of 50% of physicians writing this and the depth of ordering from the IDNs, we're seeing a lot of physicians investing huge amounts of time and energy to actually get through all of the processes, schedule the PET scans or the lumbar punctures, the MRIs. And to me, you don't do that if you don't have a strong conviction in the importance of this treatment to patients.

So personally, as I look at this, I'm extremely encouraged by where we are. I think now, for the first time since the launch, that we can look forward to the growth of this market, not just because of the prescriptions. But I look at the evidence base that we are building with our partners at Eisai on LEQEMBI. It's very clear now from the 3-year data that it probably is not going to be enough to just remove the plaque. We'll need to continue to treat patients.

And again, as I was saying earlier, with the AHEAD study, we hope to show that there is a benefit to treating earlier. So this market is going to grow and the evidence base is going to grow. It is market building, what we're doing, and that certainly takes time and patience. But as I say, I've said in the past that it's difficult to predict where we're going to go. With this quarter, I think we're seeing -- we're on a very solid track.

And I think the entry of Lilly will only accelerate the development of this marketplace.

Operator Operator

Our next question will come from Brian Abrahams with RBC Capital Markets.

Nevin Varghese Analyst

This is Nevin on for Brian here. Congrats on a good quarter, and thank you in advance for taking our questions. I just wanted to ask a little bit more about the SKYCLARYS dynamic that we're seeing, specifically about what you're seeing on patient persistence or potential discontinuation rates there. Some of the educational efforts that you're taking to kind of convince the patients to remain on therapy, even if they're not seeing the efficacy of the therapy right away. And maybe if you could speak a little bit more to some of the perceptions that patients and doctors may have on the cardiac safety and benefits there as well.

Alisha Alaimo Executive

All right. Thank you for the question. This is Alisha. First, we are very pleased with what we're seeing right now, especially globally and in the U.S. with SKYCLARYS.

And as I've mentioned before, we're past the catch-up population. And we're now really into the patient identification phase. We look at every metric from discon, compliance, adherence, start times. And when it comes to discons, we do not see anything outside of what you see in the clinical trials. And so the discontinuation rate is not anything more than obviously what we also saw in trials.

I think when it comes to efficacy of the patients, physicians have been really good on setting expectations with patients on what to expect from SKYCLARYS. The field teams do a really good job of also educating both physicians and educational materials with patients on what to expect when you start this product. And so you do see that patients tend to stay on product. And physicians are very good also about saying to patients, at least stay on it for a year, and let's talk about how you're feeling and where we're going. And what we're seeing is adherence has been actually very good.

I think the other dynamic that's playing out that you could be referring to is because we're now in the patient identification phase, you are going to see a little bit of difference from week to week and month to month. And we are adding patients every single week. We're also adding them every single month, and we acquire new data on a regular basis. And what we're seeing, at least recently, and I was sharing this with Chris the other day, we have this new AI engine that we've been deploying. And we have identified a significant number of additional coded FA patients that we didn't even have at the beginning of launch because we're starting to see that patients are engaging even more with their physicians.

And so now we're able to reach them with more efficiency and with more certainty across the board. And I think it's been very promising as we find new parent -- patients to come on.

Operator Operator

That will be from Paul Matteis with Stifel.

Paul Matteis Analyst

I think over the past year, Biogen's commentary on business development capacity has evolved a couple of times. And more recently, I think you said around $10 billion, maybe minus the HI-Bio deal. I guess, just kind of going forward in 2024 or the near to midterm, what's Biogen's appetite for bigger transactions or a Reata-like transaction? And what's the updated thinking on specific therapeutic areas or types of assets of interest?

Christopher Viehbacher Executive

Yes, I'll take that one. I think first, in terms of where we're looking, I think we're already long neuroscience. So we're probably looking outside of that space, immunology, rare diseases. As I look at Biogen, I would say we have an extremely high scientific and medical capability within the company. We have been historically a company that is in the low-volume, high-value area.

We really understand the necessity to assist patients and physicians for some expensive products to get through reimbursement, provide and sponsor genetic testing, for example. Thinking about studies and real-world evidence becomes extremely important in this. So I think there's a capability of Biogen in rare diseases.

Immunology is really an area we've been in since we started with multiple sclerosis. So I think we have the capabilities to go into those areas. I think where we are now is we're on a growth pattern. If we could find another Reata-type acquisition, I think we would look for that. But those come along pretty rarely.

It's rare that you can find a company that is that close to the market. In fact, it already launched by the time we actually had acquired that, but acquired that for a price that still creates shareholder value.

And we will continue to look, but they don't come along every day. And we're not in a position where I think we are desperate to do a deal. So we -- I think if you look at what we've done with HI-Bio, for example, as an alternative to that, being able to launch more products in the sort of 2027 to 2030 time frame is a priority for us. And that's why we're really also focused on the mid- to late-stage development process.

But we can be picky. I think also, where we look is not necessarily where everybody else is looking. You really don't create value if you enter into these auction processes. And so I think by being able to stick to those areas where we think this is a really -- this is a space where Biogen can really be a strong player, we'll avoid overpaying.

I think the other thing I would say is Biogen is a nice size. $1 billion moves the needle hugely in our company. There are a lot of bigger companies where $1 billion doesn't move the needle. And so I think we can look at assets where we have the capital that might be too small for some of the bigger players but be too expensive for some smaller players. So I think in some ways, we're in a position where we can look for assets and not necessarily be in such competitive places where, again, you risk overpaying.

But we're looking. We take a systematic view. We're not going to take any sudden left turns strategically just because I'm not sure that, that's really where the sweet spot is for Biogen. But I do think there's a number of opportunities out there. We also are doing a lot more in

research, on collaborations.

And I think one of the things I'd like to see us do is really bring a lot more assets in from an early stage because the earlier you can acquire these assets, the more shareholder value you can create.

Operator Operator

That will be from Michael Yee with Jefferies.

Michael Yee Analyst

Earlier in the call, you commented about an emerging lupus portfolio, and I know that you do have some upcoming lupus data. We've looked at the prior data. There are reasons to believe that longer treatment and a bigger study could help here. Can you just speak to your expectations? What are you looking for?

What needs to happen to move forward, et cetera, et cetera?

Priya Singhal Executive

Yes. Thank you. This is Priya Singhal. So overall, we are excited about the readout for dapi. It is upcoming in the next several weeks.

This is a partnered program, [and] collaboration is in a very good place. We are expecting a headline on top line results of the first global Phase III trial. And specifically, I want to be clear that this study is investigating in this very high unmet disease area, the safety and efficacy of dapi as an add-on to standard SLE therapy versus placebo as an add-on to standard SLE therapy. We are conducting the study in patients who have persistent active or frequent flaring, despite stable standard of care. And very similar to the Phase I and Phase II, we will be looking at efficacy assessed by BILAG-based Composite Lupus Assessment or BICLA.

But different than the Phase II study, it will take place over the week -- 48 weeks to demonstrate the long-term effect. We also increased the sample size to provide a substantial data set on safety and efficacy. Eventually and ultimately, we'll be looking for a meaningful change on the primary endpoint and key secondaries such as severe flare prevention, patients achieving low-dose activity. And we really think that BICLA is a sensitive clinically meaningful composite for SLE disease activity that requires disease improvement across all body symptoms with moderate or severe baseline activity without the need for escalation in steroids or other background medications as well as without worsening.

So we're looking forward to this in addition to an acceptable safety and tolerability profile. We think this could be really meaningful for patients suffering from SLE. So if the results warrant continuing development, at this point, we expect to have the need to run another Phase III, but we are planning some of this at risk right now.

Operator Operator

We'll now move to Eric Schmidt with Cantor Fitzgerald.

Eric Schmidt Analyst

Maybe for Chris, this call today seems to be like a relative high watermark in your tenure as CEO, given some of the initiatives that are now well in place and all that you've accomplished. And you certainly called that out in your prepared remarks. You also called out that you've got some challenges and you're not done. So what in particular is top of mind there?

Christopher Viehbacher Executive

Well, thanks for the question. I would hope it's not the high watermark because we're aiming much higher here, I can tell you. I think clearly, we've got still an MS franchise that is -- we're not done yet in terms of seeing the competitive threats. There's potentially a biosimilar for TYSABRI. We have an important patent litigation that we'll see in the fall for TECFIDERA in Europe, and there is the market exclusivity that expires in February.

So shorter term, there's always chop in the water. But I think where we have an opportunity is we have an amazing talent base inside of Biogen.

As you all know, I've been in this business a long time, seen a lot of companies. I continue just to be impressed by the scientific and medical capability that we have in the company, and we've got capital. And so I think we can do smart things with that capital. We've been busy transforming essentially passive capital into active capital.

We had 2 priority review vouchers sitting on the shelf. The innovative nature of Biogen's products is such that we don't really need those vouchers because of the innovative products we bring to market anyway. So we had this one priority review voucher sitting on the shelf for 6 years that we've now converted hopefully into an active asset. We sold it, but the objective is to spend that on milestones and business development in the second half.

If I look at HI-Bio, we took 1.5 years of Fit for Growth savings out of operating expense and transformed that into a growth opportunity with the acquisition of HI-Bio. So where I see us is I think we've been able to change the trajectory of the company. We've been able to release resources from the business and reinvest them intelligently. And we've got great people that I think can do that with tremendous results.

So I think as we look towards the future, it's really building out now the R&D portfolio, both internally and externally. I'd like to make sure we are still an innovation company going forward, that we're not just acquiring our future but really investing in that. So I think I'm now focused on the 2025 to 2030 time frame. I think we're in good shape to grow through that period.

But I think we can do more to really take advantage of the capability in R&D. And I think you'll see us continue to deploy capital with a lot of discipline, but I think be able to turn passive capital into active capital and then into active growth.

Charles Triano Executive

All right. Thank you, Chris, and thank you, everybody, for joining us today. IR team will remain available for any additional questions. Thank you.

Operator Operator

And once again, that does conclude today's conference. We thank you all for your participation. You may now disconnect.