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Q4 2022 Earnings Call

Company Participants

- Anat Ashkenazi, Executive Vice President and Chief Financial Officer
- Anne E. White, Executive Vice President and President, Lilly Neuroscience
- Daniel M. Skovronsky, Executive Vice President, Chief Scientific and Medical Officer, and President, Lilly Research Labora
- David A. Ricks, Chair and Chief Executive Officer
- Ilya Yuffa, Executive Vice President and President, Lilly International
- Joe Fletcher, Senior Vice President, Investor Relations
- Michael B. Mason, Executive Vice President and President, Lilly Diabetes
- Patrik Jonsson, Executive Vice President; President, Lilly Immunology; President, Lilly USA; and Chief Customer Offi

Other Participants

- Andrew Baum, Analyst
- Carter Gould, Analyst
- Chris Schott, Analyst
- Chris Shibutani, Analyst
- Colin Bristow, Analyst
- Evan Seigerman, Analyst
- Geoff Meacham, Analyst
- Louise Chen, Analyst
- Mohit Bansal, Analyst
- Robyn Karnauskas, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst
- Trung Huynh, Analyst
- Umer Raffat, Analyst

Presentation

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Lilly Q4 2022 Earnings Conference Call. At this time, all participants are in a listen-only mode. (Operator Instructions) And as a reminder, today's conference is being recorded.

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I would now like to turn the conference over to our host, Joe Fletcher, Senior Vice President of Investor Relations. Please go ahead.

Joe Fletcher {BIO 19356583 <GO>}

Thank you, Lovis. Good morning, and thank you all for joining us for Eli Lilly and Company's Q4 2022 Earnings Call. I'm Joe Fletcher, and joining me on today's call are Dave Ricks, Lilly's Chair and CEO; Anat Ashkenazi, Chief Financial Officer; Dr. Dan Skovronsky, Chief Scientific and Medical Officer; Anne White, President of Lilly Neuroscience; Ilya Yuffa, President of Lilly International; Jake Van Naarden, CEO of Loxo@Lilly; Mike Mason, President of Lilly Diabetes; and Patrik Jonsson, President of Lilly Immunology and Lilly USA. We're also joined by Mike Sprengnether, Kento Ueha, and Lauren Zierke from the Investor Relations team.

During this conference call, we anticipate making projections and forward-looking statements based on our current expectations. Our actual results could differ materially due to several factors, including those listed on Slide 3. Additional information concerning factors that could cause actual results to differ materially is contained in our latest Form 10-K and subsequent Forms 10-Q and 8-K filed with the Securities and Exchange Commission. The information we provide about our products and pipeline is for the benefit of the investment community. It's not intended to be promotional and is not sufficient for prescribing decisions.

As we transition to our prepared remarks, please note that our commentary will focus on non-GAAP financial measures.

And now, I'll turn the call over to Dave.

David A. Ricks {BIO 16504838 <GO>}

Okay. Thanks, Joe. 2022 was a year of strong pipeline and commercial performance for Lilly. We delivered top and bottom line growth in 2022 despite the impact of the Alimta LOE in the US and significant FX headwinds, and delivered another remarkable year of pipeline progress.

We began 2023 with multiple updates to our late-stage pipeline. In our Q2 2022 earnings call last August, we announced the filing of submissions for two assets with the FDA under an accelerated approval pathway; pirtobrutinib in mantle cell lymphoma and donanemab in early symptomatic Alzheimer's disease. Last month, we received response from the FDA on both these assets. On January 19, we announced that the FDA issued a complete response letter for accelerated approval of donanemab due to the limited number of patients with at least 12 months of drug exposure. There were no other deficiencies cited. We will continue to work with the FDA to evaluate the best pathway to make this potential treatment option available to patients and look forward to results next quarter for the TRAILBLAZER-ALZ 2 Phase 3 confirmatory trial, which will form the basis of donanemab's application for traditional approval.

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We have consistently stated that we would -- that we would expect very limited uptake before CMS supports coverage. At the time we submitted for accelerated approval, we had hoped that there would be more movement from CMS to provide access to these medicines for people with Alzheimer's disease. Unfortunately, this has not yet materialized. We maintain conviction that, given the impact of this devastating disease and significant unmet need, positive confirmatory data and FDA traditional approval should be sufficient to support global reimbursement and patient access necessary for broad use of donanemab overtime.

Also in the month of January, we received FDA approval for Jaypirca, the first and only non-covalent BTK inhibitor for adults with relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a BTK inhibitor. Jaypirca is a highly selective kinase inhibitor. This novel reversible binding mechanism and pharmacology may allow for extended targeting of the BTK pathway, following treatment with a covalent BTK inhibitor.

We are pleased with the recent approval of Jaypirca, and we remain confident in the long-term opportunity for donanemab. We also look forward to the potential launch of two of our immunology assets later this year with mirikizumab and lebrikizumab, and of tirzepatide for obesity. This current wave of new launches, along with the ongoing focus and progress in our next wave of R&D innovation, underpins our long-term outlook to drive top-tier revenue growth and expand our margins over time.

On Slide 4, you can see the progress we've made on our strategic deliverables. Excluding revenue from COVID-19 antibodies, revenue on a constant currency basis grew 10% in Q4 and 5% for the full year. Volume in our core business, again, excluding COVID-19 antibodies, grew 13% in Q4 and 12% for the year. This volume-driven performance was attributed to our key growth products, which grew 21% last quarter.

For pipeline milestones, in addition to the recent FDA approval of Jaypirca, we've shared several important updates since our Q3 earnings call. Positive Phase 3 readout and FDA and EMA acceptance of the regulatory submissions for Jardiance for adults with chronic kidney disease; the initiation of a rolling submission in the US for tirzepatide in obesity; and FDA granting a Fast Track designation for tirzepatide in obstructive sleep apnea.

We also continue to put our cash flow to work to create long-term value. In late January, we announced plans to invest an additional $450 million for expansion of our Research Triangle Park manufacturing site in North Carolina to further augment our manufacturing capacity for the years ahead. On the business development front, we closed the acquisition of Akouos to expand our gene therapy capability and we entered into a strategic research collaboration with a focus on new modalities and technologies.

Finally, we continue to return capital to investors. In Q4, we distributed nearly $900 million to shareholders via the dividend, and we announced a 15% increase to the dividend for the fifth consecutive year.

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Moving to Slide 5, you'll see a list of the key events since our Q3 earnings call, including several important regulatory, clinical, business development, and ESG updates we are discussing today or that were discussed during our guidance call on December 13.

One item I'd like to highlight is the collaboration we announced in December with EVA Pharma to deliver a sustainable supply of affordable, high-quality insulin to at least 1 million people living with diabetes in low to middle income countries, most of which are in Africa. This is an important collaboration with a local company to produce low-quality -- or low-cost, high-quality medicines, sorry. Strengthening capacity and building self reliance for insulin manufacturing within the African region will provide a more sustainable supply in the long term.

With this agreement, Lilly will sell insulin API to EVA Pharma at a significantly reduced price and provide pro bono technology transfer to enable EVA to formulate, fill, and finish insulin vials and cartridges. We are proud to be a part of this novel arrangement, which aligns with our 30x30 goal of improving access to quality healthcare for 30 million people living in limited resource settings annually by 2030.

Now, I'll turn the call over to Anat to review our Q4 and full year 2022 results.

Anat Ashkenazi {BIO 19888043 <GO>}

Thanks, Dave. Slides 6 and 7 summarize financial performance in the fourth quarter and full year 2022. I'll focus my comments on non-GAAP performance.

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As Dave mentioned, we are pleased to report 10% growth for our core business in Q4 on a constant currency basis, driven by strong volume growth. A couple of notable items affected year-over-year comparison. The first is COVID-19 antibody revenue in Q4 2022, which, compared to the prior year, declined 96% from approximately $1.1 billion in Q4 2021 to $38 million in Q4 2022. Bebtelovimab is currently not authorized for merchant's use in any US region, and we continue to expect no COVID-19 antibody revenue for 2023. Second is the continued foreign exchange headwinds compared to 2021, which resulted in the 415 basis points' strengthening of revenue growth in Q4.

Key growth products grew by 21% and accounted for 70% of our revenue this quarter. For the full year 2022, revenue, excluding revenue from COVID-19 antibodies, grew 2% or 5% on a constant currency basis. Our non-GAAP gross margin was 80.5% in Q4, an increase of approximately 440 basis points, primarily driven by lower sales of COVID-19 antibodies, partially offset by lower realized price and increased expenses due to inflation and logistics costs.

Total operating expenses declined 1% in Q4. Lowered acquired IPR&D and development milestone charges were largely offset by higher marketing, selling and administrative expenses and higher R&D expenses. Marketing, selling and administrative expenses increased 3% in Q4, primarily driven by costs supporting the launch of new products and indications, partially offset by the favorable impact of foreign exchange rates. R&D expense for the quarter increased 5%, driven by higher development expenses for late-stage assets, partially offset by favorable impact of foreign exchange rates.

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Operating income declined 7% compared to Q4 2021, driven by lower revenue, partially offset by lower operating expenses. Operating margin for Q4 was 27.4%, which includes a negative impact of approximately 330 basis points attributed to acquired IPR&D and development milestone charges. Full year operating margin was 27.8%, an increase from 26.8% in 2021.

Our Q4 effective tax rate was 7.3%, bringing our full year 2022 effective tax rate to 10.3%. As we shared during our guidance call in December, we had assumed that the 2017 Tax Act Provision for requiring capitalization and amortization of research and development expenses for tax purposes would be deferred or repealed by Congress in late 2022. However, no legislative action was taken related to this provision, which resulted in a lower effective tax rate for 2022 versus the guidance range previously shared. In addition, this provision did increase our tax payment in 2022 by approximately $1.2 billion [ph]. At the bottom line, earnings per share declined 4% in Q4 and increased 7% for the full year.

On Slide 8, we quantify the effect of price, rate, and volume on revenue growth across key geographies. This quarter, US revenue declined 10%. Excluding revenue from COVID-19 antibodies, revenue grew 11% in the US. The swap volume-driven growth was led by Verzenio, Mounjaro, and Jardiance. Net price was flat in the US this quarter. For the full year, the net price decrease of 3% in the US was in line with our expectations.

Moving to Europe, revenue in Q4 increased 8% in constant currency, driven primarily by volume growth for Jardiance, Trulicity, and Verzenio. We remain encouraged with the momentum of our business in Europe. In Japan, revenue in Q4 decreased 6% in constant currency. Revenue growth in Japan continues to be negatively impacted, albeit less so than in prior quarters, by decreased demand for several products that have lost patent exclusivity, including Alimta and Cymbalta. We expect to return to growth this year as we scale key products and launch Mounjaro.

In China, revenue grew 2% in constant currency, as continued volume growth was mostly offset by lower realized prices for Humalog as a result of the volume-based procurement process and for products listed on the NRDL, as well as by COVID-19 disruption. Revenue in the rest of the world increased 11% in constant currency this quarter, driven by approximately $130 million of one-time revenue associated with the sales of the company's rights to Alimta in Korea and Taiwan.

As shown on Slide 9, our key growth products continue to drive robust worldwide volume growth, contributing 15 percent [ph] points of volume growth this quarter. As mentioned previously, the decline in COVID-19 antibody volume was substantial in Q4 2022 and was largely offset -- and largely offset volume growth from key products. While we will face similar prior-period headwinds from COVID-19 antibody revenue through the first three quarters of 2023, our long-term growth prospects are underpinned by our innovative pipeline in key growth products including Mounjaro.

Slide 10 further highlights the contributions of our key growth products. This quarter, these brands grew 21% or 27% in constant currency, generated $5.1 billion in sales, and made up 70% of our total revenue. While Lilly's incretin portfolio understandably generates high

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interest, we continue to see tremendous growth, both in percentage and absolute terms for other key products, including Verzenio and Jardiance. Verzenio sales in the quarter grew 100%, driven mainly by the adjuvant indication. Jardiance sales grew 42%, and the product retains the leadership position in a competitive market globally. Demand for our incretin portfolio remains strong, both for Trulicity globally and Mounjaro in the US, and we remain focused on bringing additional capacity online to meet this robust demand in upcoming launches.

In terms of supply, as mentioned in our guidance call in December, given strong demand for incretin products, there have been intermittent delays at wholesalers and pharmacies in receiving certain doses levels of Mounjaro and Trulicity in the US. We continue to update the FDA on the situation, and the FDA has been posting to its website details regarding affected doses and expected timing. To meet this rapidly growing demand across our incretin business, we have announced plans to add additional substantial capacity in the years ahead. The most proximal of these efforts is our RTP site, North Carolina, where progress continues as planned, and we look forward to the start of production later this year.

Moving to Slide 11, Mounjaro's strong launch uptake continues, underpinned by differentiated efficacy profile and positive customer experiences. For Q4, approximately 75% of Mounjaro's new therapy starts are patients new to the type 2 diabetes injectable incretin class and further [ph] 10% of switches from Trulicity. As we mentioned in our Q3 earnings call in early November, we took actions in Q4 to reinforce the intended use of the Mounjaro Savings Program by type 2 diabetes patients. We indicated at that time that these actions could negatively impact new prescription volumes, but were not expected to impact net revenue. As anticipated, we believe the new prescription volumes beginning in late November were impacted by these actions with some week-by-week volatility, driven by end-of-year seasonality. We continue to build payer access for Mounjaro for type 2 diabetes. As of January 1, access stands just over 50% for patients with type 2 diabetes across commercial and Part D.

Regarding the percentage of paid scripts for Q4, we estimate the percentage of paid scripts for Mounjaro to be approximately 40%, with paid script defined as dose prescription outside the 25 non-covered co-pay card, but inclusive of the 25 covered co-pay card. As we expand payer access, the proportion of paid scripts should continue to increase.

On Slide 12, we provide an update on capital allocation. In 2022, we invested $9.6 billion to drive future growth through a combination of R&D expenditures, business development outlays, and capital investments. In addition, we returned approximately $3.5 billion to shareholders in dividends and repurchased $1.5 billion in stock.

Our capital allocation priorities remain unchanged and are oriented towards achieving our strategic deliverables of top-tier revenue growth and speeding life-changing medicines to patients. We do this through investments in our current portfolio to drive new launches, investment in our manufacturing capacity and in our future innovations for R&D and business development. And we return capital to shareholders through dividend payments and share repurchases.

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Slide 13 provides an updated 2023 financial guidance. The only change we've made from the guidance we provided in December is to update our effective tax rate, which results in an updated EPS range. During December guidance call, we shared that the effective tax rate for 2023 would be approximately 16% based on the assumed deferral or repeal of the tax provision requiring capitalization of R&D. Since this provision was not deferred or repeal in 2022 and given the uncertainty around if and when such action will take place in 2023, we have updated our tax rates from 16% to approximately 13%. This update to our effective tax rate results in new EPS range of $7.90 to $8.10 on a GAAP basis and $8.35 to $8.55 on a non-GAAP basis.

Regarding FX rates, there has been a general weakening of the dollar since we set our initial 2023 financial guidance last year. However, we're not adjusting guidance for FX changes at this time, as we're only one month into the year and FX markets can be quite volatile.

As I shared in December, the most significant headwind in revenue growth in 2023 versus 2022 will be the impact of COVID-19 antibody sales. This year-over-year comparison will be most pronounced in Q1 2023, given that we had $1.5 billion of COVID-19 antibody sales in Q1 2022. To a lesser extent, the loss of exclusivity of Alimta in the US in Q2 2022 will also impact year-over-year growth in the first half of 2023. Still, the midpoint of our 2023 revenue guidance range represents roughly 7% of growth or 50% growth for our core business, excluding COVID-19 antibodies.

This year holds tremendous promise for us to help patients, as we execute on the current wave of potential launches, while maintaining our commitment to invest in and progress future innovation. We expect this ongoing focus on disciplined execution and investment will help drive top-tier revenue growth through at least 2030.

Now, I will turn the call over to Dan to provide an update on our pipeline.

Daniel M. Skovronsky {BIO 15349505 <GO>}

Thanks, Anat. 2022 was a really productive year for Lilly R&D, as we advanced our late-stage assets of tirzepatide, donanemab, pirtobrutinib, mirikizumab, and lebrikizumab to key regulatory submissions and we obtained the approval for Mounjaro. We launched Mounjaro for type 2 diabetes in mid-2022.

As Dave shared, we received an approval last week for pirtobrutinib, now known as Jaypirca. By the end of this year, we also have the potential to launch two new immunology assets with mirikizumab and lebrikizumab. And for donanemab, we are looking forward to our Phase 3 readout mid-year, which, if positive, will form the basis of our submission for traditional approval.

In 2022, we also gained clarity on the next wave of assets that have entered or will soon enter Phase 3 registrational trials. Those are our SERD in breast cancer, our weekly insulin for diabetes, remternetug in Alzheimer's disease and, as shared in our December guidance call, we now have orforglipron and retatrutide in diabetes and obesity. Given the

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updates we provided in mid-December, today, I'll just briefly highlight progress since our last earnings call.

Slide 14 shows select pipeline opportunities as of January 30, and Slides 15 and 16 show a recap of 2022 key events and potential key events for 2023. Starting with diabetes and cardiometabolic disease, in November, we shared results from the EMPA-KIDNEY Phase 3 trial in collaboration with Boehringer Ingelheim. As the largest and broadest SGLT2 inhibitor trial and CKD to date, the results showed a significant benefit of Jardiance in reducing the relative risk of kidney disease progression or cardiovascular death by 28%, compared with placebo in people with chronic kidney disease.

The overall safety data were consistent with previous findings, confirming the well-established safety profile of Jardiance. CKD is a leading cause of death worldwide, affecting over 850 million people globally and 37 million in the US. We've submitted to the FDA and EMA for approval and expect to make submissions to other regulatory agencies in the coming months.

In January, we started QWINT-1, a Phase 3 study comparing fixed-dose escalation of Lilly's weekly insulin to insulin glargine in insulin-naive type 2 diabetes patients. With this initiation, all five studies in the QWINT Phase 3 program are now underway.

Moving to earlier-stage assets in our diabetes and CV pipeline, in Q4, we advanced two assets into Phase 2 that aim to lower Lp(a), a well-known risk factor for atherosclerotic cardiovascular disease. The first is an oral inhibitor, a small molecule that disrupts the interaction between the apoA protein and the lipoprotein particle; and the second uses siRNA to disrupt the production of apoA in the liver. We shared proof-of-concept data on the siRNA asset during our December 2021 R&D Investor Meeting. This is our second siRNA asset to advance to Phase 2, following our ANGPTL3 siRNA, which entered Phase 2 earlier in 2022.

We also recently moved an siRNA asset targeting apoC3 in cardiovascular disease into Phase 1. Our genetic medicines portfolio is advancing, and we remain optimistic about the prospect of improving cardiovascular outcomes with these molecules. Lastly, we discontinued our Phase 1 KHK inhibitor.

In oncology, we are, of course, pleased with the recent approval of Jaypirca, and we look forward to continuing the substantial ongoing development program for the molecule in the years ahead. Jaypirca is the second product approved from our 2019 Loxo Oncology acquisition, which reshaped our oncology efforts at Lilly. Loxo@Lilly's growing NME portfolio now includes a number of emerging assets shown in our pipeline, including our FGFR3 program, which recently dosed its first patient. Also, in Q4, we dosed the first patient in EMBER-4, our second Phase 3 trial for imlunestrant, our oral SERD. EMBER-4 will study imlunestrant in the adjuvant setting as a sequential monotherapy in patients who previously received two to five years of adjuvant endocrine therapy for ER+, HER2- early breast cancer with increased risk of recurrence.

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Lastly, turning to Verzenio, as noted in our guidance call, at the San Antonio Breast Cancer Symposium in December, we shared the latest interim analysis for monarchE, our adjuvant high risk early breast cancer study of abemaciclib in combination with endocrine therapy for the treatment of adult patients with HR+, HER2-, node-positive early breast cancer at high risk of recurrence. We've now submitted an sNDA to the US FDA to potentially expand our adjuvant indication beyond the currently indicated cohort 1, Ki-67 greater than 20% population.

In immunology, we're looking forward to potential FDA approvals later this year for mirikizumab in ulcerative colitis, which we expect in the first half of the year; and lebrikizumab in atopic dermatitis, which we expect in the second half of the year. Looking earlier in our immunology pipeline, as mentioned in our guidance call, we presented exciting proof-of-concept results for our PD-1 agonist antibody, peresolimab, in rheumatoid arthritis at the ACR Conference in November, and we have now initiated global, dose-ranging Phase 2b study.

Moving to neuroscience, we've advanced our -- into Phase 2 our P2X7 inhibitor for chronic pain. Lilly acquired rights to this asset from Asahi Kasei Pharma in early 2021. With regards to donanemab, as Dave mentioned, the sole deficiency cited by the FDA to our submission for accelerated approval was the number of patients with at least 12 months of drug exposure. The Phase 2 TRAILBLAZER-ALZ trial, on which the accelerated approval application was based, allowed patients to complete their course of treatment with donanemab, when they reached a predefined level of amyloid plaque clearance. Due to the speed of plaque reduction that we saw, many patients were able to stop dosing as early as six months into treatment, resulting in fewer patients receiving 12 months or more of donanemab dosing. We remain confident in the potential donanemab as a new treatment for people with early symptomatic Alzheimer's disease, and look forward to sharing results from the Phase 3 TRAILBLAZER-ALZ 2 study in Q2 of this year.

In summary, while 2022 was an outstanding year of pipeline progress, we are fully focused on the work we need to do in 2023 to make our next set of potential medicines a reality for patients. We look forward to providing additional updates throughout the year.

Now, I turn the call back to Dave.

David A. Ricks {BIO 16504838 <GO>}

Thanks, Dan. Before we move to Q&A, let me summarize the progress we made during 2022. We delivered strong revenue growth in our core business, propelled by our key growth products. We launched Mounjaro for patients with type 2 diabetes, while advancing and expanding our development program for tirzepatide, including the start of the SURMOUNT-MMO outcome study and the initiation of a rolling submission for chronic weight management.

In 2022, we submitted regulatory applications for important pipeline products, like mirikizumab, pirtobrutinib, and lebrikizumab. And in 2023, we've already received approval for Jaypirca and are poised to advance donanemab in the regulatory process, assuming positive data from the TRAILBLAZER-ALZ 2 Phase 3 study. In addition, we

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continue to invest in our pipeline, our capacity, our capabilities, and our people. Finally, we returned $5 billion to shareholders via the dividend and share repurchases; and for the fifth consecutive year, announced a 15% dividend increase for 2023.

With continued growth in Mounjaro and our key products, including Verzenio, Jardiance, and Taltz, we expect our core business revenue to grow by mid-teens in 2023. We are energized by the launch opportunities before us this year and know strong launch execution is key to our long-term success. Taken together, we believe that we are well positioned to deliver top-tier revenue growth through at least 2030 and to deliver on Lilly's mission to make life better for people around the world.

So now, I'll turn it over to Joe to moderate the Q&A session.

Joe Fletcher {BIO 19356583 <GO>}

Thanks, Dave. We'd like to take questions from as many callers as possible and conclude our call in a timely manner. So, we ask that you limit to one question or one two-part question per caller, as we'll end the call at 11:15. Lovis, please go ahead and provide the instructions for the Q&A session, and we're ready for the first caller.

Questions And Answers

Operator

Thank you. (Operator Instructions) Our first question is from Colin Bristow from UBS. Please go ahead.

Q - Colin Bristow {BIO 17216671 <GO>}

Hey, good morning, and thanks for taking the questions. Just first on Mounjaro, it looks like the net price dropped again from 3Q to 4Q. Can you just walk us through what specifically drove that and just update us on how you expect this to trend over the course of the year? And then just maybe looking sort of out to the future of your obesity portfolio beyond GGG, do you have any interest in mechanisms that target sort of the mitochondrial uncoupling side of the equation? That would be helpful. Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Colin. We'll go to Mike for the first question on gross to net and price for Mounjaro, and then hand over to Dan for kind of broader obesity mechanistic commentary. Mike?

A - Michael B. Mason {BIO 18347681 <GO>}

Yeah. Thanks for the question. I think the best way to answer that is to kind of take a look at what we saw as kind of our Mounjaro paid scripts in Q4 and then how we think that'll progress over '23. In the fourth quarter, we classified about 40% of Mounjaro's scripts as paid, which we define as patients that aren't supported by our $25 non-covered savings program.

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Now, our savings program, as we discussed at launch, was designed to bridge people living with type 2 diabetes to access. As we discussed in the Q3 earnings call, we have adjusted the program to better ensure it's being used for people living only with type 2 diabetes. These adjustments included removing our $25 non-covered benefit from our savings card for new patients. We didn't make any adjustments for existing patients who's saying [ph] these cards that are set to expire on June of this year -- June 30. As expected, these changes have reduced new patient start volume, while increasing the percent of new patients with a history of diabetes treatments and the percent with formulary coverage.

I think the way I would look at our savings program right now for new patients is that we have graduated from the bridging program and now, are kind of the type of savings program, really focused on covered patients that you would do in kind of a normal lifecycle of a product. So thus, we expect that Mounjaro's percent of paid scripts and the net revenue per script to increase through 2023, as we continue to increase access and grow new starts.

We remain disciplined in our access discussions so we can maximize long-term value. From the start, our value -- our approach was to make sure, that we capture value in the long term versus the short term, and we've remain very disciplined on that. We have just over 50% access for lives in Part D and commercial segments for people living with type 2 diabetes. We're very pleased where we're at on the access front and the way our contractors -- contracting has turned out at this point. So, hopefully, that helps provide some color to our gross to net in Q4. Thanks.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Mike.

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Thanks, Colin, for your question on future mechanisms for treating obesity. I can assure you, we're not done innovating on behalf of people with obesity. There's a lot we can still do. I think keep your eyes open for more to come from Lilly labs on incretin and related types of mechanisms, but also broadly interested in a variety of new non-incretin-based mechanisms.

You specifically asked about one, mitochondrial uncoupling. But there are several others, I think, that also have promise for patients. I just sort of put a note of caution though, treating obesity, we need to have a very high bar for the types of medicines we develop, remembering that this is a chronic, often lifetime disease and a highly prevalent population. We need medicines that, first and foremost, are extremely safe and really highly well tolerated for patients. So that's what we're looking for in future mechanisms.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Colin. Lovis, next question?

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The next question is from the line of Chris Schott from JP Morgan. Please go ahead.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks very much. One follow-up on the last set of questions. Is it still reasonable to think about a net Mounjaro price that could be above that of Trulicity as we look out to 2024 or whenever you achieve kind of comparable payer access?

And then my question was on donanemab. I know there wasn't a huge revenue opportunity tied to the accelerated approval. But I think you had talked about using that gap between accelerated approval and full approval to really ramp physician education and infrastructure, et cetera. How do you kind of manage through that now, I guess, where we're going to have maybe a full approval that could be occurring, closer into a CMS decision? So just maybe elaborate a bit about what that means for donanemab over time? Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Chris. All right. We'll go to Mike for the question about Mounjaro price kind of over time and how it might compare to Trulicity, and then to Anne on your donanemab question about activity that would occur to ramp up HCP education. Mike?

A - Michael B. Mason {BIO 18347681 <GO>}

Yeah. Thanks for the question. I can't get into real specifics about our net price for obvious reasons, but maybe I'll address the question this way. I mean, if you look at -- when we have -- when we reach -- we think we'll reach broad access for Mounjaro and reach, ultimately, similar access levels that we have for Trulicity. There's nothing differently about how we'll promote or how we'll support patients on Mounjaro versus Trulicity. So, at the end of the day, it will come down to our net price negotiations with payers. We believe that Mounjaro has a better profile. We invest a lot of innovation in there, and we do believe that it should have a better net price than Trulicity.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Mike. Anne?

A - Anne E. White {BIO 20764375 <GO>}

Yeah. Thanks, Chris, for the question on physician education and readiness. So, as you said, the accelerated approval is not going to provide access for the vast majority of patients. So, it doesn't impact us in that way. And obviously, accelerated approval would have made it maybe a little bit easier to do some of the things that we wanted to do, but there's still a great deal that we can do -- actually have been doing to make sure that the healthcare system is ready for these medicines. So, we begin working on that. Things such as developing the diagnostic ecosystem are incredibly important, making sure that there's better, integrated Alzheimer's disease pathways to make sure that physicians can properly identify, refer, infuse these patients. So that's the area of focus right now.

Certainly, diagnostics are a key area of focus for Lilly. We've continued to expand our PET network to make sure that we're ready for patient diagnosis. And then as well, we continue

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to be committed to P-tau blood tests and intend to launch that this year. So, many things going on that I think can make us very ready for traditional approval and making sure that people can access these medicines.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Chris, for the questions. Lovis, next question?

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Operator

The next question is from Seamus Fernandez from Guggenheim. Please go ahead.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Great. Thanks for the questions. So Dan, I wanted to ask you if you could talk a little bit about where you see the oral GLP-1 space developing and how your product is likely to be positioned. A little bit of this, I think, is also what you think the unmet need is outside of where the sort of very robust weight loss that we see from Mounjaro is. And then just an add-on to that, how do you see the oral market developing in terms of other potential agonists? Is that something that Lilly is pursuing and hoping to further develop combinations there as well? Thanks.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Seamus. Yeah, we'll go to Dan on those questions.

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Yeah. Thanks, Seamus. I'll get started. Maybe Mike wants to add on, on some of the marketplace questions. But clearly, obesity is a huge problem in the US and around the world. I think 100 million Americans potentially with obesity and reaching 1 billion people around the world pretty soon. That's probably not a market that even all of the interested companies could address solely with injectables. So, just given the scope of the problem around the world, we're going to need orals. Ultimately, it's our goal to have orals that can match the safety, tolerability, and efficacy of injectables. I think our oral GLP-1 is our first attempt in this space and has really good prospects for meeting that initial goal, but then -- noting, of course, that the injectables are going to get better over time and the orals will catch up as well.

The second part of your question was, how do the orals catch up. And I think you're sort of alluding to an obvious issue, which is, right now, our oral GLP-1 and other orals in the space are single mechanism, single incretin agonists. I think we've seen with great drugs like Trulicity and competitive products what single agonists against GLP-1 can achieve. It's not as good, I think, as what can be achieved with dual agonism for tirzepatide or, hopefully, even triple agonism with GGG. And so, you can bet we are working on oral solutions that can bring additional incretin activity to patients in a pill. Nothing ready to disclose today, but we're working hard.

A - Joe Fletcher {BIO 19356583 <GO>}

Okay. Thanks, Dan. All right. Lovis, next question?

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Operator

Next question is from the line of Geoff Meacham from Bank of America. Please go ahead.

Q - Geoff Meacham {BIO 21252662 <GO>}

Good morning, guys. Thanks for the question. I have two related ones on tirzepatide. Dan, I know you have SURMOUNT-4 coming up, which is the maintenance study. But how has your thinking evolved, if at all, on the potential duration of tirzepatide use, either based on longer exposure from clinical studies or in the real world? And do you think that could inform payer discussions?

And then, Mike, on Mounjaro, a moving target, but how does the prescriber base as of today compare with Trulicity? I'm trying to get a sense for maybe the endocrinology versus primary care mix and utilization in obesity. Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Great. Thank you, Geoff. So, we'll go to Dan for the question on SURMOUNT-4 and duration of tirzepatide, and then to Mike on the question of how the prescriber base for Mounjaro compares to Trulicity.

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Yeah, sure. As I was just saying, I mean, obesity is clearly a chronic, often lifetime disease. And for such diseases, the patients often need to take therapy for chronically -- potentially the life of the disease here. A lot of times in medicine that doesn't happen, of course. People come off of therapies, because either the therapy is working and they think they don't it need anymore, or there's a benefit they can't see. I'm not sure either of those are the case for a drug like tirzepatide. People clearly can observe the benefits the drug is having on their health. And perhaps, unfortunately, but not different really than any other drug that we have for any other disease, when you stop taking the drug, it's likely that it can no longer work, and patients may see that as well.

So, I think those factors will combine to have a pretty long duration of therapy. We have to wait and see in the marketplace. Maybe Mike has some early signals from patients, but it's still pretty early on.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Dan. Mike?

A - Michael B. Mason {BIO 18347681 <GO>}

No hard -- yeah, no hard data yet, Dan, on that. But qualitatively, what we hear is what -- patients who've used Mounjaro, what they like and what they realize once they start using it is that it really does reduce the appetite and they enjoy the benefits of reducing appetite. It helps them lose their -- lose weight and stop being as consumed as much during the day about eating. And we do know that when -- what we heard from our investigators and our studies is that when people stop taking Mounjaro that their appetite

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goes back to the levels it was before. So, that's something very noticeable, something that they -- that a patient values from taking the therapy and then when they stop the therapy, they then see this reversed.

And so, we do believe that people are going to stop and see if they can lose weight. If they can, great. But I do think that they're going to see a very powerful signal very quickly to reinforce going back on the product. So, I do think that will help reinforce the chronic use of tirzepatide for type 2 diabetes and, eventually, for obesity if we get approved.

The question on Trulicity. Mounjaro -- if you looked at Mounjaro's use right now and compare it to how many customer for using that versus Trulicity at this time, it's a lot broader population than that we saw with Trulicity, just because the market's a lot bigger, a lot more people are riding the treatment. If you compare Mounjaro to the number of Trulicity riders today, there are more people riding Trulicity, just because it's been on the market longer. They've gone through the adoption curve and Trulicity has better access, and especially in Medicaid that drives additional prescribers to use that.

So overall, I'd say the Mounjaro is within the universe of the doctors who write Trulicity at this point.

A - Joe Fletcher {BIO 19356583 <GO>}

Thank you, Geoff, for the question. Lovis, next question?

Operator

The next question is from Tim Anderson from Wolfe Research. Please go ahead.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. I have a question on donanemab. I'm wondering if Lilly would agree that there is highly likely going to be higher ARIA-E and ARIA-H rates with your drug versus lecanemab when TRAILBLAZER-ALZ 2 reports out. The prior data would certainly suggest that. If so, relative to lecanemab, doesn't that create a potential risk-benefit conundrum for FDA, assuming efficacy comes in around the same levels? I guess, the bottom line here, is there a regulatory concern to contemplate? Maybe this is why FDA issued the CRL. They want to see the full results from your second study. They don't just want to capture a few more patients to bring that total to 100, or am I being too bearish here? Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Tim, for the question. We'll go to Dan for this.

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Yeah. Maybe I answer the second part of the question first, which is around why did the FDA issue the CRL. I think that the FDA regulations actually suggest that FDA should list all deficiencies in the CRL. We were pretty explicit copying some of the FDA's own words here to investors about what was in the CRL. It didn't discuss issues like ARIA. It was focused on the 12-month exposure. So, nothing further to speculate there.

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I think your question on rates of ARIA-E and ARIA-H comparing across drugs is a complicated one. We did this head-to-head study against aducanumab. I think it's important to use studies like that to compare rates of ARIA, because we've learned that grades of ARIA are highly dependent on the type of patients who enroll the stage of disease and underlying pathology, baseline characteristics of their brain scans, which are different across lecanemab trials and donanemab trials, as well as exactly how you do the MRIs and read them.

So, I'm personally not going to get worked up about rates of asymptomatic radiographic-only ARIA in any drug. I don't think anyone really understands what that means. What we should be focused on though is rates of symptomatic ARIA, so patients who have ARIA that turns into something they experience, not just a radiographic binding and, particularly, rates of serious adverse events resulting from ARIA. We know that in some patients ARIA can be dangerous, even fatal, as we've seen from lecanemab experiences. So, that's what we'll be looking out for.

I think we still have all the caveats about cross-trial comparisons here, but it's a bit easier to compare those symptomatic or serious events. I think in TRAILBLAZER 1, our numbers were very similar to other members of the class. In TRAILBLAZER 4, the numbers look very, very good for that. And we'll wait and see what we have in TRAILBLAZER 2. The level of concern over that is not high.

A - Joe Fletcher {BIO 19356583 <GO>}

Thank you. Lovis, next question?

Operator

The next question is from the line of Terence Flynn from Morgan Stanley. Please go ahead.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks so much for taking the question. Maybe a two-part one for me. I guess, first, on Mounjaro manufacturing, I was just wondering if you can tell us if the FDA has completed the inspection of your new North Carolina facility yet. And then the other question relates to tirzepatide for obesity. I was wondering if you've had any initial payer conversations yet and if you're planning to use a priority review voucher for that filing. Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Terence. I think I'll hand over to Anat for commentary on your manufacturing question, and then to Mike on the question about whether there's been any payer conversations on obesity.

A - Anat Ashkenazi {BIO 19888043 <GO>}

Terence, as to your question on the RTP site, North Carolina, it's progressing on schedule as we had planned. We can't comment on specifics on the FDA interactions, but we're expecting that site to start producing this year, and it's progressing towards that goal. I will mention, important to think about -- we talk about RTP, I think, because of the proximal

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nature of when this site's going to come online. Obviously, this is the next large node that's going to come online in terms of capacity for incretin portfolio.

But we are making substantial investments beyond RTP. So, we have announced a second site in North Carolina, a very large site in Concord, and we've announced the expansion of the RTP site, additional sites in north of Indianapolis and a site in Ireland. And as we look at our capital investments in manufacturing sites this year alone, it's probably the largest we've ever had, doubling what we had in 2022. We're looking at about $3.3 billion of investment just this year.

So, we're looking at substantial expansion of capacity really across the globe to support, not just Mounjaro, obviously, but the rest of the portfolio, and we have visibility into what's coming, as well as the fact that as we've talked about before, we have several products that are part of the same manufacturing network and the same auto-injector platform. So, that helps us kind of build that capacity across the Lilly portfolio.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Anat. Mike, on the second question?

A - Michael B. Mason {BIO 18347681 <GO>}

Yeah. I think a good thing to focus on is access and obesity. I mean, you look at the massive size of the obesity market, 110 million people in the US, 650 million people globally, but you really see that -- historically, that the obesity market has really been slow to develop. And it's really because the treatments haven't been adequate. So, the kind of -- the question we had going into this market was, if a safe and efficacious treatment was developed, would consumers and healthcare professionals and payers be interested in using it. Well, based on what we've seen in the marketplace over the past year and on a market research, it's clear that consumers and healthcare professionals will adopt an efficacious, safe, anti-obesity medication if patients can have access to it.

So it does come down to payer access, and we're highly focused on doing that. Noble recently stated in their call that 40 million Americans have access to obesity and the way they talked about it, what's payer access and employers opting into that. So, if that's where we're at today, that would be a great starting point for access. We're deep into conversations with payers to understand the market and all that. Access discussions haven't started yet, but will shortly. But our focus long term is to improve access for anti-obesity medications. We are investing significantly to demonstrate the potential health outcome benefits for people using tirzepatide who live with obesity. We're also investing in Phase 3 programs for people who live with obesity and sleep apnea or heart failure, and these should unlock large segments' access for people who live with obesity in commercial and, we hope, Part D.

In addition, in my career, I've seen the power of consumer interest in helping to improve access for medication. And what we've seen over the last year is that people who live with obesity are highly engaged and willing to do much access-effective treatments. They will have an important role and voice with employers and the congressional representatives who advocate for access. So, while I think it will take time to establish our ultimate actions

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goal, I'm more encouraged than ever by our potential to unlock the obesity market and help a lot of people. So, I'm encouraged, but obviously, a lot of work still to be done.

A - Joe Fletcher {BIO 19356583 <GO>}

Thank you, both, and thanks, Terence, for the question. Lovis, next question?

Operator

The next question is from Steve Scala from Cowen. Please go ahead.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. A question for Anat. I'm not going to get the legislative particulars correct. But just to be clear, doesn't Lilly typically guide on tax rate, assuming an adverse US situation and doesn't typically adjust that until late in the year? And this year, it is assuming no adverse situation, but much earlier in the year? If so, can you clarify why you were doing something different this year, since it is a profound impact on earnings? And if I could just add on Lp(a), Dave, Lilly is way behind. How can you catch up? Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Steve. I'll go to Anat for the question on the tax rate assumptions, and then I'll go to Dan for your Lp(a) question.

A - Anat Ashkenazi {BIO 19888043 <GO>}

Thanks, Steve. So, here is how we look at this, and I wouldn't read too much into it. Last year, we had assumed, based on very broad support for a change in this 2017 tax provision that this will, in fact, be enacted by Congress. We assumed late in the year, but it hasn't happened. So, at this point, the only thing we're doing is reflecting reality of the situation we're in. If it does get repealed or deferred, obviously, we'll update accordingly. I don't think the likelihood of that is zero. So it still could happen this year, but it does take Congress -- Congress will need to act to get this going. So, we're simply reflecting the current situation.

A - Joe Fletcher {BIO 19356583 <GO>}

Dan?

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Okay. I'll start with the Lp(a) question. We have two Lp(a) programs. Maybe the easiest one to comment on first is the oral program. This is a first-in-class; I think, probably the only one in clinic here. An oral medication against this target is really a huge feat of molecular engineering. I'm super excited to see the data from this molecule developed and, obviously, the market opportunity for an oral drug for such a widespread condition is very important.

In terms of the siRNA, you're right to note that a competitor is ahead of us and really just starting the CVOT study. It's a long road to get these drugs to market with the outcome

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studies needed here to show the benefit that probably don't get into our differentiation strategy. But of course, we have some ideas here, and we'll move as quickly as possible. I don't see this as a winner-take-all space.

A - David A. Ricks {BIO 16504838 <GO>}

Maybe just to add, Steve -- add on the LP(a) comment, I think we feel good about where we are with that. But just on the tax thing, there is a difference here, where you described it as adverse or beneficial, right? So, the -- from a GAAP and non-GAAP accounting, of course, it's a benefit on EPS growth. But actually, from a cash perspective, it goes the other way. So we just wanted to be clear upfront, because it's not a one-way benefit we're taking early in the year. There's an adverse cash impact throughout the year and a positive effect on the P&L. It's a little bit different from maybe past assumptions we've made.

A - Joe Fletcher {BIO 19356583 <GO>}

Lovis, next question?

Operator

The next question is from Louise Chen from Cantor. Please go ahead.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my question. So, I wanted to ask you. What do you think is the minimum amount of relative risk reduction you'd have to see in an outcome study for obesity for payers to be convinced that there's something here? Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Louise. Mike, do you want to chime in on that around the minimum amount of relative risk reduction we'd expect in an outcome study for obesity?

A - Michael B. Mason {BIO 18347681 <GO>}

Yeah. That was a good question. I mean, first of all, I don't think it's a binary point where all payers are looking for that outcome in order to provide access. I think you're going to see a lot of payers -- you already see a lot of payers who can provide access for that. And we have an extensive Phase 3 program only in CV outcomes, but also the sleep apnea and heart failure to begin to really talk about heart outcomes for many patients who live with obesity.

With the CV outcomes that we have today, I mean, we're quite confident in our program, and based on what we see with surrogate risk reduction in blood pressure and lipids, we're fairly confident in our CV profile, as well as what we saw with the SURPASS data and our meta-analysis in the SURPASS program. So, I won't give you the exact number, but I think we're pleased with where we're at, and I think we'll be able to demonstrate outcomes that payers will be excited about.

A - Joe Fletcher {BIO 19356583 <GO>}

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Thanks, Louise, for the question. Lovis, next question?

Operator

And that comes from David Risinger from SVB Securities. Please go ahead.

A - Joe Fletcher {BIO 19356583 <GO>}

Dave, are you there? Okay. Looks like we don't have Dave, or he's on mute. Lovis, next question.

Operator

The next question is from Chris Shibutani from Goldman Sachs. Please go ahead.

Q - Chris Shibutani {BIO 3202082 <GO>}

Thank you. If I can ask a question on Mounjaro and the interplay with Trulicity. You've commented in the past that in terms of patients on Mounjaro, it has been about less than 10%. That seems to be a little bit higher now. Can you share any thoughts and observations about how you see this progressing on the forward through this year?

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Chris, for the question. Mike, we'll go to you for that question on the, I guess, cannibalization from Trulicity figure and how that will progress.

A - Michael B. Mason {BIO 18347681 <GO>}

Okay. Yeah. I mean, on that, nothing has changed over what we had talked about earlier that less than 10% of our scripts we get for Mounjaro come from Trulicity. That hasn't changed over time. It's still a little bit less than 10%.

A - Joe Fletcher {BIO 19356583 <GO>}

Okay. Thank you. Lovis, next question?

Operator

And that comes from Umer Raffat from Evercore. Please go ahead.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, guys, thanks for taking my question. There's been a heightened investor focus, I feel, along the Phase 3 primary endpoint for donanemab now. And I wonder if there's been any incremental interactions and/or agreement with FDA on the primary endpoint for Phase 3. It's a question I get a lot from investors. And also, how are you thinking about this upcoming Phase 3? If there were to be a scenario where the MMRM on CDR doesn't agree with high ADAS [ph] on the patient analysis? Thank you.

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A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Umer. We'll go to Dan for the question on endpoints.

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Yeah. Thanks. Thanks. Clearly, I think there's a lot we can learn from competitor readouts here. And so, looking at the lecanemab data, in our eyes, I think it actually further validates an endpoint like ADAS. If you just look at the -- for a spot [ph], for example, there's a lot more homogeneity in effect on an endpoint like ADAS versus CDR Sum of Boxes. So, we feel more confident, I would say, than ever before that an endpoint like that is the right way to go. On the other hand, I think the -- you could take the position that since lecanemab hit CDR Sum of Boxes, people might say, well, then it's achievable, and you guys should do it too. So, there's some pushes and some takes there. But on the whole, still feeling good about ADAS as a primary outcome.

When you ask though, what happens if you hit one outcome and not the other, that's a -- surely a difficult situation to be in. We want to understand why that happened if that were to happen. Were there irregularities in CDR Sum of Boxes that could explain it, what did the rest of the secondaries look like. Always best to hit all of your outcomes in a clinical trial. Failing that, you want to hit your primary and as many secondaries as possible. So, let's wait and see.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Umer. Lovis, next question?

Operator

Next question is from Mohit Bansal from Wells Fargo. Please go ahead.

Q - Mohit Bansal {BIO 18070890 <GO>}

Great. Thank you very much for taking my question. Maybe a question regarding your next-generation Alzheimer's drug. I cannot pronounce the name, but remternetug? I mean, I'll learn it. But how does it differ or is similar versus donanemab? Asking, because -- I mean, you're running a Phase 3 trial with subcu here. So, what would be the read-through for this particular asset based on the outcome of donanemab Phase 3 trial?

A - Joe Fletcher {BIO 19356583 <GO>}

Dan, you want to talk a little bit about remternetug?

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Yeah. I think you've got it basically right. Remternetug is a new medicine, a new molecule, but it's an antibody against the same type of epitope that donanemab has, which is this N3pG form of beta. So, a very equivalent mechanism of action. Maybe a little better potency and certainly better drug properties, including no ADAs and formulation things. So, the rationale here is to give improved dosing options to patients. Could we get even faster plaque clearance? Could it be with fewer doses? Could it be subcutaneous. Those

are the types of things that we're currently exploring. The Phase 3 is designed with a bit of a run-in. We're in that portion right now to finalize our dosing strategy and then expand it.

Obviously, if donanemab is disappointing, there would be read-through, through remternetug. On the other hand, if donanemab exceeds expectations, I would expect that to read through as well.

A - Joe Fletcher {BIO 19356583 <GO>}

Thank you, Mohit. Lovis, next question?

Operator

The next question is Evan Seigerman from BMO. Please go ahead.

Q - Evan Seigerman {BIO 18922817 <GO>}

Hi, guys, thank you so much for taking the question. While much of the discussion on Medicare coverage has been Alzheimer's, we know that Medicare really doesn't pay for obesity drugs. Can you just talk about your efforts to help Medicare patients get coverage for obesity drugs, including potentially, Mounjaro, if when approved? Maybe add some parameters around what that additional population could look like from a revenue opportunity perspective? Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Evan, for the question. I'll hand over to Mike. Mike, do you want to talk about the potential for Medicare to cover obesity?

A - Michael B. Mason {BIO 18347681 <GO>}

Okay, sure. Yeah, good question. I mean, it's going to take legislative action in order to allow anti-obesity medications to be covered on Medicare Part D. So, there is the Treat and Reduce Obesity Act. The acronym for that is TROA. And there's a large growing bipartisan support for TROA. A little over 100 congressmen, senators -- Congresspeople and senators are behind the program. And it's growing more and more support across the -- across Washington. We are eager to see an advanced legislative process. It would be great for the company -- country. America needs to take action and drastically reduce the number of people with obesity and this legislation would be an important step toward this goal. We'll support the legislation and continue to work to advocate for it.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Mike. Lovis, next question?

Operator

The next question is from Trung Huynh from Credit Suisse. Please go ahead.

Q - Trung Huynh {BIO 19379786 <GO>}

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Thanks for squeezing me in. I'm Trung Huynh from Credit Suisse. Last month, the American Academy of Pediatrics released their guidelines to treat childhood obesity. In those guidelines, they recommended a lifestyle intervention, obviously, as the core component. But also, they said they would consider treatment with anti-obesity medications. So, I thought -- what's your thoughts on anti-obesity medications in children? Is this a scenario that you are moving into or considering moving into? Do you have any trials with children or adolescents? Thank you.

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A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Trung, for the question. Mike, over to you again. Comment on these recent guidelines that were put out?

A - Michael B. Mason {BIO 18347681 <GO>}

Yeah. Yeah, thanks. I mean, this is a significant unmet need. Back to the question that we asked earlier about the Treat and Reduce Obesity Act. We need to improve the health of America. We have too many people who live with obesity in the US, and that includes, unfortunately, adolescents and kids. So, I think they took the right action in order to really identify this as an issue that healthcare professionals do need to pay close attention to. We obviously always advocate for diet and exercise as the first approach of this. But if that's not successful, then your really only option at that point is medication treatment. We do think it's important and responsible for us to test the appetite in kids and adolescents, and we have activity ongoing to do that.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Mike, and thanks, Trung, for the question. Lovis, next question?

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Operator

The next question is from Carter Gould from Barclays. Please go ahead.

Q - Carter Gould {BIO 21330584 <GO>}

Great. Thank you for taking the question. I guess, one for Anat. Back in December, you highlighted austerity measures in Europe as a potential risk. At that time, that was a bit of a unique position. We hadn't heard that from many companies since that time. We've heard kind of similar messaging from some, but not all. And apologies if I missed it, I don't think I heard anything today on this front. So, I know it's only been sort of 45 days or so since you made those comments. But any advances in sort of how you're thinking about this? And any specific products or countries we should think about that impact? Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Carter, for the question. We're actually going to hand this over to Ilya Yuffa, who's our President of Lilly International, to comment on the European austerity measures.

A - Ilya Yuffa {BIO 21952737 <GO>}

Yeah, I appreciate the question. Listen, there have been a number of markets in Europe that have taken some austerity measures, partially due to Ukraine crisis and energy crisis

and inflation in Europe. We have seen Germany, France -- obviously, the UK voluntary system, we think, is broken and so, we exited that. And so, we -- there are some austerity measures in there. We've contemplated that into our guidance for '23. And the overall impact is modest relative to historical declines in price in prior years. We expect that to continue to be in that mid-single digit decline in price in Europe.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Ilya, and thanks, Carter, for the question. Lovis, next question?

Operator

The next question is from Andrew Baum from Citi. Please go ahead.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. A question on US commercial access for GLP-1 agonist. First, could you share with us how you're thinking about modeling the impact of the IRA in terms of GLP-1 uptake increasing as a result of the co-pay cap and, additionally, benefiting from the reduction in free drug program. How significant is it, given the patients still got to find $2,000 per annum?

And then second, in relation to the oral DPP-4 market, which is still a very, very substantial $14 billion market, you have a category of drugs extensively, which may offer considerable advantages in efficacy for glycemia and white. But I'm reminded of the stickiness of the sulfonylureas in the prior period. To what extent do you think managed market is going to preclude your ability to penetrate that segment with all GLP-1s just on the basis of generic DPP-4s? Thank you.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Andrew, for the wide-ranging question on diabetes. I'll hand over to Mike first to talk about your question regarding potential impact of the IRA on access for GLP-1; and then the second question around how oral GLP might fit in, given the stickiness of some of the older diabetes medications. Mike?

A - Michael B. Mason {BIO 18347681 <GO>}

Yeah. Good questions. On the IRA side of it, it will benefit patients who live with diabetes who use GLPs and are in Medicare Part D. Their out-of-pocket cost will go down. It may have a -- I would say, a small or moderate impact on GLP sales or just probably lower rates of abandonment than what we'd see at higher out-of-pocket costs.

As it comes to the oral DPP-4, the perceptions of oral DPP-4s have really declined over the last five years and really being replaced by SGLT2s and GLP-2s. So, I don't see much of an impact of DPP-4s going off path in the US or other markets.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Mike. And Lovis, I think we have one final question in the queue. So, let's go to the last question.

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Operator

Thank you, and that's from Robyn Karnauskas from Truist -- please -- I'm sorry, Truist Securities. Please go ahead.

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Great. Thanks for taking the question. I was just thinking more about some of the launches that are coming up, but I know these maybe a little bit out. But for mirikizumab -- and I always get these things wrong, sorry. But for UC, can you just talk a little bit about, given how much promotion there's been for Skyrizi and Rinvoq, as you move into also Crohn's with data reading out soon, like, how do you see, like, competing in that market? Is it -- can you start launching? Do you have to be DTC-heavy, because it seems like they're very prominent. Like, what about the launch dynamics?

And then second, for lebrikizumab, same question here. Atopic dermatitis is getting pretty crowded. What kind of pushes and pulls might you need to use to get quicker uptake in atopic derm? Thanks.

A - Joe Fletcher {BIO 19356583 <GO>}

Thanks, Robyn, for the questions. I'll go to Patrik Jonsson for both of these; first on mirikizumab and competition in the UC market, and then on lebrikizumab. Patrik?

A - Patrik Jonsson {BIO 22620517 <GO>}

Thank you very much. Well, overall, we feel very good with the data we have seen on mirikizumab. If we look at the 52 weeks, we have more than 50% clinical remission, and we see statistical and clinically meaningful improvements across both clinical symptomatic, endoscopic, and histologic endpoints. What I think is important that, if you look at the patient populations with ulcerative colitis, we saw the same results across the bio-naive and the bio-failure patients. So, I think we're extremely well positioned for a launch here. We also demonstrated on a fact, but it's extremely important for patients' bowel urgency. More than 40% of patients were either completely or almost bowel urgency-free at week 52. So, therefore, we believe we have a first-in-class asset here that probably initially will be used mainly second line for those that haven't responded appropriately to TNFs and similar. But we believe that, long term, we are positioned for a first-line placement in treatment of ulcerative colitis.

And yeah, so the outlook for mirikizumab. It's exciting. From a competitive landscape perspective, we don't have head-to-head data. But if we compare the data we have seen so far, we believe that miri compares very favorable, DOPE [ph] versus what's currently in the marketplace, as well as what's in the pipeline with other companies across JAK inhibitors, S1Ps and other IL-23s as well. So, exciting to launch miri the first half of this year.

When it comes to lebri, I think actually, we are uniquely positioned to really upgrade the expected outcomes of patients with atopic dermatitis. We have here an asset that is actually targeting the most relevant cytokine when it comes to treating atopic dermatitis, IL-13, and it does that with a high binding affinity, high potency and a slow off rate. And I

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think that probably explains the data that we have seen so far. We're extremely pleased with the Phase 3 data, and we saw more than 80% of patients achieving skin clearance at week 16, maintaining that at week 52, but also very importantly, statistical and clinically meaningful improvements across both each, which is probably the most disturbing factor for patients with atopic dermatitis, sleep and quality of life. And we saw similar results across both the Q2W and Q4W formulation.

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We actually believe that lebrikizumab has the potential to become a first-line biologic. It's important though to have in mind that we announced the submission at the Q3 earnings call, and we expect the -- a traditional regulatory pathway. Yes, we will not launch until most likely Q4 of 2023. But a lot of excitement from both healthcare providers, support leader community, as well on the payers to get lebri to the market.

A - Joe Fletcher {BIO 19356583 <GO>}

Thank you, Patrik. Dave, to wrap up?

A - David A. Ricks {BIO 16504838 <GO>}

Great. I think that's the last question. I appreciate the questions across the portfolio. And we appreciate your participation in today's earnings call and your interest in our company. 2022 was another productive year for the company, and we generated strong financial results and delivered important pipeline progress in each of our core therapeutic areas on behalf of the patients we serve. We aim to continue our momentum in 2023 and execute on the meaningful launch and pipeline opportunities that we have ahead of us.

So, thanks for dialing in, and please follow up with IR if you have questions that we didn't get to you today. Have a great day.

Operator

Thank you. And ladies and gentlemen, this does conclude our conference for today. And this conference will be made available for replay beginning at 1 o'clock today, running through February 9 at midnight. And you may access the AT&T replay system at anytime by dialing 866-207-1041 and entering the access code 4283950. International dialers can call 402-970-0847. Again, those numbers are 1-866-207-1041 and 402-970-0847, with the access code 4283950.

And that does conclude our conference for today. Thank you for your participation and for using AT&T Event Conferencing. You may now disconnect.

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