# Q3 2023 Earnings Call

## Company Participants

- Anat Ashkenazi, EVP & CFO
- Anne E. White, Executive Vice President, President
- Daniel M. Skovronsky, Executive Vice President, Chief Scientific and Medical Officer, President
- David A. Ricks, Chairman of the Board, President, Chief Executive Officer
- Ilya Yuffa, President of Lilly International
- Joe Fletcher, VP, Investor Relations
- Michael Mason, EVP & President of Lilly Diabetes

## Other Participants

- Carter Gould, Analyst
- Chris Schott, Analyst
- Chris Shibutani, Analyst
- David Risinger, Analyst
- Evan Seigerman, Analyst
- Geoffrey Meacham, Analyst
- Laura, Analyst
- Louise Chen, Analyst
- Mohit Bansal, Analyst
- Nicole, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst
- Trung Hun, Analyst
- Umer Raffat, Analyst

## Presentation

### Operator

Ladies and gentlemen, thank you for standing by and welcome to the Lilly Q3 2023 Earnings Call. At this time, all participants are on a listen-only mode. Later, we will be conducting a question-and-answer session and instructions will be given at that time. (Operator Instructions)

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

## Joe Fletcher {BIO 23100909 <GO>}

Good morning, and thank you, Paul, and thanks, everybody, for joining us for Eli Lilly and Company's Q3 2023 earnings call. I'm Joe Fletcher, Senior Vice President of Investor Relations. 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, President of Loxo at Lilly; Mike Mason, President of Lilly Diabetes and Obesity; and Patrik Jonsson, President of Lilly Immunology and Lilly U.S.A. We're also joined by Michaela Irons, Mike Springnether and Lauren Zierki of the IR 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.

Now I'll turn over the call to Dave.

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

Thanks Joe. In Q3, Lilly continued the progress we've made so far this year. We delivered strong financial results, continued to advance our R&D pipeline and invested in our future through several business development transactions.

As you can see on slide four, we continue to make progress against our strategic deliverables this quarter. Excluding revenue from the olanzapine portfolio and COVID-19 antibodies, revenue grew 24%. Our new products and growth products combined contributed approximately 17 percentage points towards volume growth, with over 12 percentage points coming from our growth products.

Last week, we announced that the FDA approved Omvoh for the treatment of moderately to severely active ulcerative colitis in adults. This marks Lily's first approval in the US for a type of inflammatory bowel disease, and it's important for Lilly's growth in its immunology portfolio. In addition to the FDA approval for Omvoh, we had several other important pipeline updates since our last earnings call. Specifically, Jardiance was approved by the

FDA for the treatment of adults with chronic kidney disease at-risk of progression. And we reported positive Phase III results from the VIVID-1 trial, which evaluated the safety and efficacy of mirikizumab for the treatment of adults with moderately to severely active Crohn's disease.

In Q3, we announced that the FDA issued a complete response letter for lebrikizumab based on inspection findings at a third-party manufacturer. The letter stated no concerns with the clinical data package, the safety or the label. We will continue to work with a third-party manufacturer and the FDA to address the findings to make lebrikizumab available to patients as quickly as possible.

In terms of business development, we once again had a very active quarter. In Q3, we completed the divestiture of the olanzapine portfolio, which will further enable us to focus on our current and new product launches. The financial impact of this transaction is reflected in the Q3 results. Additionally, within the quarter, we completed the acquisition of two clinical-stage companies adding to our Phase II portfolio, DICE Therapeutics and Versanis Bio, as well as the acquisition of Emergence Therapeutics and Sigilon Therapeutics.

We also announced that we reached an agreement to acquire point Biopharma, which if approved, has the potential to expand our oncology capabilities into next-generation radioligand therapies. And lastly, we distributed over $1 billion dollars in dividends this quarter.

On Slide 5, you'll see a list of key events since our Q2 call, including several important regulatory, clinical and other updates we are sharing today.

Now let me turn the call over to Anat to review our Q3 results.

**Anat Ashkenazi** {BIO 19888043 <GO>}

Thanks, Dave.

Slide 6 summarizes financial performance in the third quarter of 2023. I'll focus my comments on non-GAAP performance. We're pleased with the strong financial performance this quarter, highlighted by continued acceleration of revenue growth representing robust momentum in our core business. Q3 revenue increased 37% versus Q3 2022. Excluding revenue from the olanzapine portfolio and from the COVID-19 antibodies, revenue increased 24% in Q3. This represents a quarter-over-quarter acceleration revenue growth driven by Mounjaro and the continued strong performance of Verzenio and Jardiance.

Gross margin as a percent of revenue increased to 81.7%. Gross margin in the quarter benefited from the divestiture of the olanzapine portfolio, the absence of COVID-19 antibody sales in Q3 2023, and high realized prices, partially offset by increases in manufacturing expenses.

Marketing, selling and administrative expenses increased 12%, primarily driven by higher expenses associated with new product launches and additional indications, as well as compensation and benefit costs.

R&D expenses increased 34%, primarily driven by higher development expenses for late-stage assets and additional investments in early-stage research. This quarter, we recognized acquired IPR&D charges of $2.98 billion, which negatively impacted EPS by $3.29. In Q3 2022 acquired IPR&D charges totaled $62 million or $0.06 of EPS.

Operating income decreased 71% in Q3, driven by acquired IPR&D charges, partially offset by higher revenue associated with the divestiture of the olanzapine portfolio. Operating income as a percent of revenue was approximately 6% for the quarter and reflected a negative impact of approximately 31 percentage points attributable to acquired IPR&D charges.

Our Q3 effective tax rate was 84.6%. This represents an increase of approximately 74 percentage points compared to the same period in 2022. The increase in the effective tax rate was primarily driven by the nondeductible acquired IPR&D charges incurred this quarter. Other than the impact of acquired IPR&D, the underlying tax rate was consistent with previously provided guidance.

At the bottom line, we delivered earnings per share of $0.10 in Q3, a 95% decrease versus Q3 2022, inclusive of an increase of $1.22 of EPS associated with the divestiture of the olanzapine portfolio and a negative impact of $3.29 from the acquired IPR&D charges.

On Slide 8, we quantify the effect of price, rate and volume on revenue growth. This quarter, U.S. revenue increased 21%. When excluding revenue from the olanzapine portfolio and COVID-19 antibodies, U.S. revenue grew 32%, driven by robust growth of Mounjaro, Verzenio and Jardiance. Net price in the U.S. increased 13% for the quarter driven by Mounjaro access and savings cards dynamics. Excluding Mounjaro, net price in the U.S. decreased by high single digits.

As mentioned in prior earnings calls, we expected Mounjaro Access and Saving Card dynamics to have a meaningful impact on reported U.S. price changes in the second half of 2023, which was evident in Q3.

Europe continued to post robust growth against -- again this quarter. Excluding revenue from the olanzapine divestiture, revenue was up 7% in constant currency, driven by volume growth of 11% primarily from Verzenio, Jardiance and Taltz. For Japan, Q3 revenue decreased 16% in constant currency. Excluding Mounjaro, which had a onetime upfront payment associated with the sales collaboration agreement in the base period, revenue in Japan decreased 3% in constant currency driven primarily by customer buying patterns related to Angeli.

Moving to China, revenue increased 20% in constant currency with volume growth of 25%, partially offset by price declines. Volume growth in Q3 was driven by Tyvyt and Verzenio. We're encouraged by the growth we have seen this year in China, revenue in the rest of

the world increased 23% in constant currency as volume growth of 28% was driven by Mounjaro, Verzenio and Jardiance.

Slide 9 shows the contribution to worldwide volume growth by product category. As you can see, the new products and growth product categories combined contributed approximately 17 percentage points of volume growth for the quarter. The absence of revenue from COVID-19 antibodies compared to the base period was a headwind of nearly 6 percentage points to volume in Q3. This headwind will abate as COVID-19 antibody sales were minimal after the third quarter of 2022. Lastly, revenue from the sales of rights to the olanzapine portfolio delivered nearly 22% points of growth this quarter.

Slide 10 provides additional perspective across our product categories. First, I would like to highlight Verzenio, which saw worldwide sales growth of 68% in Q3, driven by robust volume growth. The continued positive momentum is driven by the early breast cancer indication, with steady performance in the metastatic indication. Jardiance continued its strong 2023 performance, with worldwide revenue growth of 22% for the quarter.

As you heard earlier in Q3, Jardiance was approved by the FDA for the treatment of adult with chronic kidney disease at risk of progression. In Q3, we saw worldwide Trulicity revenue decline 10% as volume growth in the U.S. was more than offset by lower prices driven by changes to estimates for rebates and discounts in both periods as well as unfavorable segment mix and higher contracted rebates.

In the international markets, Trulicity volume continues to be affected by measures we have taken to minimize potential disruption to existing patients, including communications to health care professionals not to start new patients on Trulicity.

Moving to Slide 11. We continue to be pleased with the strong performance of Mounjaro as more type 2 diabetes patients benefit from the medicine. Mounjaro revenue grew to just over $1.4 billion globally this quarter, up from $980 million the previous quarter. In Q3, we continued to make progress in expanding access to Mounjaro. As of October 1st, access for patients with type 2 diabetes in the U.S. reached 78% in aggregate across commercial and Part D, including 85% access for commercial patients. This expanded access gives more patients the opportunity to start therapy on Mounjaro for type 2 diabetes.

As communicated last quarter, since the $25 noncovered co-pay card program expired on June 30, we now considered all prescriptions paid. As a reminder, we define paid scripts as those prescriptions outside of the $25 noncovered co-pay card, but inclusive of the $25 covered co-pay card. We expect Mounjaro net price will continue to benefit from the higher percentage of paid prescriptions, but will also continue to face a headwind from more rebated volume as access improves. Looking forward to the end of the year, with increased access, we expect to continue to see overall growth in prescription trends.

In terms of Mounjaro supply, we're continuing to make progress on our manufacturing expansion agenda. Given strong demand, we continue to experience tight supply throughout most of Q3, which impacted results for the quarter. Most recently, U.S. product

shipments have increased, and inventory levels of U.S. wholesalers have improved, with all doses of Mounjaro now listed as available on the FDA shortage website.

While supply constraints have eased in the U.S., outside the U.S., Trulicity and -- outside the U.S., Trulicity's and Mounjaro's supply remains tight, which materially impacted performance in these regions. With device assembly online at RTP, we are on track to achieve our goal of doubling capacity by the end of this year from where we were a year ago and are gradually increasing production each quarter. We're also continuing to focus on other parts of the supply chain as demand is expected to remain high and production bottlenecks may shift over time.

As we mentioned in last quarter's earnings call, we are moving forward with different presentation of Mounjaro to reach more patients around the world faster. We have launched with a single dose vial in Australia and plan to launch in other markets outside the U.S. in the coming weeks and months. The introduction of a single dose vial presentation in these geographies is intended to serve as a bridge to a multi-dose click pen, which we expect will be available starting in 2024. We're also preparing for a potential launch of tirzepatide for obesity in the U.S. later this year. Our auto-injector capacity and output continues to increase, and we look forward to bringing tirzepatide to more patients in the months and years ahead.

On Slide 12, we provide an update on capital allocation. In the first 9 months of 2023, we invested nearly $12 billion in our future growth through a combination of R&D expenditures, capital investments and business development outlays. In addition, we returned nearly $4 billion to shareholders in dividends and share repurchases.

Slide 13 presents our updated 2023 financial guidance. Guidance for the first 4 line items, including revenue, gross margin percent, marketing and selling and administrative expenses and R&D expense is unchanged. I would note that we are trending towards the higher end of our estimates for gross margin in the top end of our ranges for operating expense categories. You'll see that we've updated guidance for acquired IPR&D charges, OID, tax rate and EPS to reflect the inclusion of IPR&D charges for completed transactions through Q3, and year-to-date results and equity investments in GAAP guidance. These updates do not include the effect of potential charges associated with pending or future business development transactions after Q3. We will provide our initial 2024 guidance when we report Q4 results.

Now I will turn the call over to Dan to highlight our progress in R&D.

## **Daniel M. Skovronsky** {BIO 15349505 <GO>}

Thanks, Anat. This quarter, we had significant pipeline progress as well as a high volume of activity at the major medical congresses where we presented new data on multiple products across all of our therapeutic areas.

Starting with oncology. Since our last earnings call, we announced top line results from the LIBRETTO-531 study evaluating Retevmo versus physician's choice of multi-kinase inhibitors as an initial treatment for patients with advanced or metastatic RET-medullary

thyroid cancer. As we presented at ESMO, the study met its primary endpoint, demonstrating a 72% improvement in progression-free survival compared to cabozantinib or vandetanib. These data should establish Retevmo as the standard of care for the initial systemic treatment of patients with progressive advanced RET-mutant medullary thyroid cancer, and we have work to do to ensure that all of these patients are identified and properly diagnosed.

We also shared detailed data from the Phase III LIBRETTO-431 study at ESMO in October, showing that Retevmo more than doubled progression-free survival compared to chemotherapy plus pembrolizumab in patients with advanced or metastatic RET fusion-positive non-small cell lung cancer. We hope these data, in addition to others recently published for other driver positive lung cancers will help accelerate genomic profiling at lung cancer diagnosis to guide initial treatment selection. The results of LIBRETTO-531 and of LIBRETTO-431 were each simultaneously published in the New England Journal of Medicine.

Also at ESMO, we shared LANDMARK 5 year results from a preplanned interim analysis of the Phase III MONARCH-E study evaluating Verzenio in combination with endocrine therapy, compared to endocrine therapy alone in patients with HR-positive HER2-negative node positive early breast cancer at a high risk of recurrence. The impact of 2 years of Verzenio treatment is observed well beyond the treatment period, reducing the risk of long-term recurrence by 32% at 5 years. These data reinforce 2 years of Verzenio plus endocrine therapy as the standard of care for high-risk early breast cancer patients.

Lastly, we shared data on imlunestrant, our oral SERD being studied in Phase III as a single agent and in combination therapy. The data shared included the first clinical data for imlunestrant in combination with everolimus or alpelisib as well as updated monotherapy from the Phase I AMBER study in patients with ER-positive HER2-negative advanced breast cancer. We hope imlunestrant could be an important future endocrine therapy backbone in certain settings of breast cancer. And these new data show that medicine can be safely combined with other agents utilized with endocrine therapy in advanced breast cancer.

Looking earlier in our oncology pipeline, we shared preclinical data on 3 of our new pipeline agents at the triple meeting on Molecular Targets and Cancer Therapeutics in October. We shared preclinical data for, first, a highly potent inhibitor of KRAS G12D that is selective against wild-type KRAS. Second, a highly potent and isoform selective pan-KRAS inhibitor, with activity against a broad spectrum of the most common activating KRAS mutations and high selectivity over wild-type HRAS and NRAS. And third, a fully human monoclonal anti-nectin-40a antibody conjugated to a topoisomerase inhibitor. These programs are among the next slate of oncology agents we expect to enter the clinic over the next year. They represent years of focused work to create potentially differentiated molecules against exacting target product profiles.

Turning to our diabetes and obesity portfolio. In Q3, we announced the FDA approval of Jardiance for treatment of adults with chronic kidney disease at risk of progression. In the EMPA kidney Phase III trial, Jardiance significantly reduced the risk of kidney disease progression and cardiovascular deaths in adults with CKD. This approval adds to the

treatment options for the more than 35 million adults in the U.S. affected by chronic kidney disease.

Since the last earnings call, we presented detailed results from the SURMOUNT-3 Phase III clinical trial at the Obesity Week Conference in October, with the results simultaneously published in Nature Medicine. Also in October, we presented detailed results from the SURMOUNT-4 study at EASD. These results will be subsequently published in a top-tier peer-reviewed medical journal. Data from these Phase III trials of tirzepatide showed that participants achieved up to 26.6% total mean weight loss. The detailed results from these studies clearly show the importance of continued therapy for sustained weight management, and that, if approved, tirzepatide could be an important part of obesity management for those having difficulty maintaining weight loss with diet and exercise alone.

Our pipeline, as shown on Slide 14, now includes a high-dose tirzepatide NILEX in Phase II since we have initiated the study exploring higher doses of tirzepatide in participants with type 2 diabetes and obesity.

Earlier in the pipeline, we presented Phase I data on muvalaplin at the European Society of Cardiology Congress with simultaneous publication in Jama. Muvalaplin is the first oral agent specifically developed to lower LP(a) levels. In this Phase I study, muvalaplin was well tolerated by participants and resulted in dose-dependent lowering of Lp(a) of up to 65%. Muvalaplin is currently in Phase II.

As shown on Slide 14, we have advanced our SCAP siRNA into Phase I for NASH. We've also completed our acquisition of Versanis and now show bimagrumab in Phase II. We are excited about the potential combination of bimagrumab and tirzepatide.

Lastly, we're happy to share that since our last earnings call, the Retatrutide Triumph Phase III core registration trials are now all actively enrolling to pursue simultaneous indications for chronic weight management, obstructive sleep apnea and knee osteoarthritis.

Turning to our neuroscience portfolio. The FDA has shared with us that the donanemab review will extend into Q1 2024, needing additional time to complete their review. We've completed submissions in Europe and Japan, and submissions to other global regulatory authorities are either completed or underway.

Recently, at the clinical trials in Alzheimer's Disease Meeting, we presented new insights from donanemab development program during a symposium session. As part of this symposium, we shared ARIA data from a pooled analysis that included more than 2,000 participants dosed with donanemab and explored ARIA-E association across a number of baseline variables, highlighting a few key factors most strongly associated with ARIA risk, including baseline amyloid levels, evidence of a prior bleed and high blood pressure. Interestingly, this data also suggested use of antihypertensives decreased the risk of ARIA. Additionally, we shared analysis from our open-label addendum of over 1,000 patients treated with donanemab. These results included a post-hoc analysis of patients with no

brain tow and demonstrated similar or even stronger biomarker results than our main TRAILBLAZER-ALZ 2 study.

In a separate post-hoc analysis from the TRAILBLAZER-ALZ Phase III study, related to activities of daily living and independence in people with early symptomatic Alzheimer's disease, we showed that compared to placebo, people treated with donanemab preserved more of their ability to perform many of the items measured, including their ability to make meals, to use appliances, keep appointments, perform past times and be safely left unattended. We also shared an update on our validation data for our plasma PTAO217 test for identifying amyloid-positive patients, demonstrating robust performance of this immunoassay. We expect to have this test commercially available in a phased approach first as a laboratory developed test by the end of this year. As you recall, we use plasma PTAO217 to identify presymptomatic individuals for a TRAILBLAZER-ALZ 3 trial. This is an event-driven trial, and we have now recruited a sufficient number of qualifying presymptomatic participants and expect to have efficacy results within 3 years.

We're excited to announce today that our Otoferlin gene therapy asset from Akos has begun dosing patients in a Phase I/II trial for hearing loss. In immunology, as Dave noted, we're happy to have the FDA approval for Omvoh for the treatment of moderately to severely active ulcerative colitis in adults. This approval offers new hope for patients who are searching for an effective option that can offer rapid and lasting improvements. Omvoh will be approved -- available to patients in the U.S. in the coming weeks.

We're also excited to have the Phase III readout for this molecule, mirikizumab, in Crohn's disease. In the VIVID-1 Phase III study, mirikizumab met the co-primary in all major secondary endpoints compared to placebo. Mirikizumab demonstrated clinical remission and endoscopic response for patients with moderately to severely active Crohn's disease through 52 weeks. We were thrilled to see that more than half of participants on mirikizumab achieved clinical remission at 1 year, and that robust efficacy was seen in both participants who are naive to biologic therapy as well as participants who previously failed a prior biologic therapy. Helping patients achieve long-term clinical remission is a key goal for us in our pursuit of treatments for inflammatory bowel disease. These new data in Crohn's disease build on the high levels of long-term remissions seen with mirikizumab for ulcerative colitis and help reinforce the differentiation of this important potential medicine. This successful Phase III trial will be the basis of global regulatory submissions for Crohn's disease.

As Dave noted earlier, in Q3, we announced that the FDA issued a complete response letter for lebrikizumab based on findings at a third-party manufacturer. In Q3, we completed the acquisition of DICE and now reflect the 2 oral IL-17 assets, DICE 853 and DICE 006 in Phase I and Phase II of our pipeline, respectively. Additionally, 2 new molecules began Phase II studies in immunology this quarter. First, our CD200R monoclonal antibody, known as ucenprubart for atopic dermatitis; and second, our RIPK1 inhibitor for rheumatoid arthritis. We've removed our BTLA monoclonal antibody agonist from Phase II in our pipeline after the Phase IIa study failed to demonstrate efficacy.

Q3 was another productive quarter for R&D at Lilly. I'll now turn the call back to Dave for closing remarks.

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

Thank you, Dan. Before we go into Q&A, let me briefly sum up our progress in the third quarter. This quarter, revenue growth accelerated as our recently launched product portfolio continued to gain momentum, of course led by Mounjaro. Excluding revenue from the divestiture of the olanzapine portfolio and the sale of COVID-19 antibodies in 2022, revenue grew 24%, driven again by Mounjaro, Verzenio as well as Jardiance.

By continuing to invest in recent and coming launches, late-stage medicines and early phase capabilities as well as in business development, we are confident that we have positioned ourselves for growth now and in the coming years, with the opportunity for continued margin expansion. We achieved meaningful advances in our late-stage pipeline, with the FDA approval of Omvoh for the treatment of moderately to severely active ulcerative colitis; as well as Jardiance for the treatment of adults with chronic kidney disease; and the positive Phase III VIVID-1 results for mirikizumab for adults with moderately to severely active Crohn's disease.

Looking forward, we are expecting regulatory responses before the end of the year on our submissions for pirtobrutinib, an accelerated approval in CLL, as well as tirzepatide for obesity.

In Q3, we completed several targeted acquisitions intended to bolster our early and mid-stage portfolio. Directly following the quarter, we also announced an agreement to acquire POINT Biopharma, which will further expand our R&D capabilities in oncology. Lastly, we returned over $1 billion to shareholders via the dividend.

A few weeks ago, we announced several leadership changes. Mike Mason, our Executive Vice President and President of Lilly Diabetes and Obesity, will retire from the company at the end of 2023 after 34 years with Lilly. In his current role, Mike has overseen tirzepatide's late-stage development and an unprecedented type 2 diabetes launch. Mike leaves behind an enduring legacy that reflects his deep compassion for patients and his commitment to our people. With this being Mike's last earnings call, I would like to thank him for his many years of outstanding service to Lilly, and wish him the best in his next chapter of life.

Patrick Johnson will assume leadership of Lilly Diabetes and Obesity, in addition to his current responsibilities as President of Lilly USA. And Dan Skovronsky, our Chief Scientific Officer and President of Lilly Research Labs, will take on the additional role of President of Lilly Immunology from Patrick.

And in a related move, David Hyman, is assuming the role of Chief Medical Officer for the company from Dan, overseeing the full Lilly portfolio. Leigh Ann Pusey, our Executive Vice President for Corporate Affairs and Communications, has decided to leave the company at the end of 2023. Leigh Ann has left a lasting impact on Lilly and the patients we serve, and we're grateful for her many contributions over the past 6 years.

So as we begin this new chapter of growth for our company, we are very confident that our deep experience of our leadership team will allow us to continue to accelerate our efforts to make medicines and be more effective and more innovative in the years ahead.

So now let me turn the call over to Joe, and he'll moderate the Q&A session.

### Joe Fletcher {BIO 23100909 <GO>}

Thanks, Dave. We'd like to take questions from as many callers as possible and conclude the call in a timely manner. So consistent with last quarter. We'll respond to one question per caller so ask that you limit to one question per caller as we'll aim to-end the call at 10 AM. If you have more than one question, you can re-enter the queue and we'll get to your question if time allows.

So Paul, please provide the instructions for the Q&A session and we are ready for the first caller.

## Questions And Answers

### Operator

Thank you. At this time we'll be conducting a Q&A session. (Operator Instructions) The first question today is coming from Tim Anderson from Wolfe Research. Tim, your line is live.

### Q - Nicole {BIO 21224965 <GO>}

Thank you so much. I have a question on obesity and persistence on therapy, which I think has been a big question, Mark. I know you have formally launched yet, but guessing you might have some idea. A best guess, if nothing else. So is your in your view, is this going to be like most other drug categories where persistence on therapy is often low? I think the rule of thumb is that at the 1-year mark, 50% of patients drop off chronic medicines. So really, the question is, if you took 100 patients who start on one of these contemporary obesity drugs, how many of that initial 100 would likely still be on therapy, let's say, 3 or 4 or 5 years down the road?

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Tim. Mike, do you would you like to weigh-in on the persistence of therapy on obesity?

### A - Michael Mason {BIO 18347681 <GO>}

Yeah, thanks for the question. Maybe I'll first answer with the data that we do have, because it's hard to speculate on what it's going to be for obesity. The best data we have for tirzepatide is in type 2 diabetes patients who started Mounjaro prior to our savings card changes last fall. Mounjaro persistency for those patients is tracking higher than those patients that were started on Trulicity and Ozempic over that same period of time. So while it's too early to project the average length of therapy or how many out of 100 will still be on therapy after a couple of years. I think this early data is encouraging.

As for obesity, time is going to tell. I think we've all looked at WEGOBI data. But I don't think this is the right benchmark at this point because of Novo supply constraints. And there's been just a very dynamic market. I think as you said, this -- having persistency on a chronic treatment isn't just an issue for anti-obesity medications, it's a goal for all chronic treatments. And I think what's different about obesity is that on many chronic treatments, consumers don't feel differently, are experiencing any acute impacts from stopping treatments. So what we've seen in the SURMOUNT clinical trials with tirzepatide is that some consumers will feel their appetite increase and experience weight regain when they stop tirzepatide. And so this should help reinforce treatment adherence.

Seeing in our market research, how important it is for people who live with obesity to lose weight and maintain it, I do think you're going to see just a high motivation. I see people have lost weight that they do want to maintain it. And we do know our SURMOUNT program that chronic use of tirzepatide is a good component, an important component of maintaining weight loss. So it's too early to project it, but I do think there's things that's rolling in favor of tirzepatide

Having a good length of therapy in the obesity patients.

### Q - Nicole {BIO 21224965 <GO>}

Thanks, Mike.

### A - Joe Fletcher {BIO 23100909 <GO>}

Next question, Paul.

### Operator

The next question is coming from Seamus Fernandez from Guggenheim. Seamus, your line is live.

### Q - Seamus Fernandez {BIO 7525186 <GO>}

Great, thanks so much for the question. So I really wanted to drill into orforglipron and those Phase III programs. Dan, I was just hoping that you could clarify for the market if there is any monitoring in that study related to liver enzyme elevations. I think there was one case in the Phase-II diabetes study that you conducted. Just wanted to know if there's any related concerns associated with that or if, if, if this is kind of as expected? And you know, a, a an all, all hands-on deck moving forward opportunity? Thanks.

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

Thanks, Seamus. Yeah, I like the way you phrased it, all hands on deck moving forward on orforglipron. We're really excited about this molecule. In terms of liver safety, I think we commented before that what we saw in Phase-II is put -- we thought it'd be probably be typical for a trial of that nature in this population. So not a heightened level of concern, but always concerned about safety going into Phase III from a variety of factors, including for all small molecules, especially liver function. So it's routine in our Phase III studies across the portfolio to monitor liver function and sure we're doing that in orforglipron. But

I'm not aware of any special precautions there. So super-excited about that, that program is going fast.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Dan. Paul. Next question?

### Operator

The next question is from Terence Flynn from Morgan Stanley. Terence, your line is live.

### Q - Terence Flynn {BIO 15030404 <GO>}

Great, thanks so much for, for taking the questions. Anat, you had mentioned shifting the data of your 2024 guidance call to early next year. Just wanted to know what drove that change? And if you can assure us that there are no issues with the tirzepatide obesity review and/or manufacturing? Thank you.

### A - Anat Ashkenazi {BIO 19888043 <GO>}

Sure. So let me first start with reassuring you that there are no issues behind our decision to move the guidance date to, or have it aligned with our Q4 earnings call. What it does do is it does help us have the year-end full results when we provide guidance for 2024. So previously, if we didn't have that investors had to look at guidance range for the year and estimates based on midpoint, et cetera. This does enable us to close the year and then have a full view into 2024. It is aligned with our internal planning processes as well. And, obviously, is the way most companies and I believe all companies in our industry do that.

So nothing unique going into that other than just having the full dataset for 2023.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thank you, Anat. Paul, next question?

### Operator

The next question is coming from Mohit Bansal from Wells Fargo. Mohit, your line is live.

### Q - Mohit Bansal {BIO 18070890 <GO>}

Great, thank you very much for taking my question. And my question is regarding the P-tau217 biomarker data ypou have shown at CTAD. It seems like the predictability is getting to 94% of these tests. Even C2N was pretty good. So do you have any thoughts on at this point, how close are we to actually make this -- bring this to prime time and when the donanemab gets approved, Do you think this could be the test doctors use or it will still take some time to get to?

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Mohit, for the question. You broke up a little bit there, but. I think we got the gist. I'll hand-off to Anne.

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

Yes. As we shared at CTAD, we were pleased with the data that we saw. And we're also pleased to see progress across the field in blood biomarkers. We definitely believe that this is incredibly important to drive access and early diagnosis in Alzheimer's disease. So you've seen us invest in a number of fronts, our own P-tau217, but also partnering with others who are working on good tests to elevate the area. So it's a strategy of raising all boats.

But yes, we did share our data, and we intend to make this available in a phased approach commercially at an LDT starting at the end of this year in a couple of sites and then continuing to expand over 2024. But at the same time, you'll see us continue to publish the data. We think that what's incredibly important in the field is that good correlated data, particularly with amyloid PET, which is the gold standard in diagnosis, is published and shared. So that we can continue to make sure that we have high-quality tests out there. So that's part of our goal with delivering this test is to really set a standard for what a blood test should look like.

So look forward to hearing more over the next coming months as we publish that data and then make that more broadly available.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Anne, and thanks Mohit for the question. Paul, next question?

### Operator

The next question is coming from Louise Chen from Cantor. Louise. Your line is live.

### Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my questions. So I want to ask you, do you think the approval of additional oral -- potential approval of additional oral diabetes drug could

Impact the pricing for injectables? Why or why not? Thank you.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Louise for the question. I'll hand over to Mike about the potential approval for other oral diabetes drugs and potential impact on injectables.

### A - Michael Mason {BIO 18347681 <GO>}

No, I don't think that will have an impact. I mean, traditionally, we don't see a new class of diabetes agents coming in. And in fact, in the current class, usually, the competition happens within a specific class within the diabetes market.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Mike. Paul, next question?

## Operator

The next question is from Geoff Meacham from Bank of America. Geoff, your line is live.

## Q - Geoffrey Meacham {BIO 21252662 <GO>}

Good morning, everyone. Thanks for the question. I just had one on tirzepatide supply. I know you guys have a plant in North Carolina and another one coming online next year. But if you look beyond that, if you have demand anywhere near what's modeled, and even outside of obesity and diabetes, you know, obviously supply could remain tight. So the question is, is there a threshold of, of treated patients like in the near-term that will inform your decision on adding manufacturing capacity and how much does the outlook orforglipron have on that? Thank you.

## A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Geoff, for the question. I'll hand over to Dave.

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

Yeah, thanks. Geoff, obviously a hot topic, and we work on this multiple hours everyday. You're citing the announcements we've made. And we made, as Anat mentioned, great progress on our manufacturing agenda. RTP is sort of on track to deliver on its goal as we exit the year and then that kind of in-market volume following that conquered, which is a few hours away and kind of a replica site, also well on track for coming online in '24. So that's good news in the IRMA presentation, which is the what we call our auto injector that you know from Trulicity and the current presentation for Mounjaro in the U.S.

We've announced previously that we're introducing now a single-use vial presentation ex U.S. so that we are now basically sitting on approvals and can have patients have access to the medication. That will follow then by a multiuse injector that uses different property, plant and equipment than what we're talking about here. So a couple of things to point out. You're noting kind of new greenfield site expansions we've rightfully made a big deal out of. We're not done with those. I think you might hear more about that in the future. Of course, we are aggressively planning that and not banking on orforglipron to rescue us from this. We think that there is a need to take up parenteral incretin supply pretty dramatically from the current levels, and we plan to do that.

But that will be in a combination of the current syringe-based auto-injector, the vial capacity we've already talked about; the multiuse injector, which will come online sometime next year, and is a highly efficient play for us because it uses current systems, different ones from the auto-injector. And then there's third-party agreements that have been ongoing in the background. And to point out here, we are not going to only have one, we have a diverse portfolio of third parties, recognizing that the probability of full supply from any one is probably less than one, but buying up as much capacity as available in all those systems.

So we've got, I think, all hands on deck, a phrase that as used earlier. I mean this is really all hands on deck and it's a problem we work every day. So we're not at all happy with the

capacity we've announced already. You'll see more. Some we don't announce. That will just layer in to the volume we ship. And of course, long term, new presentations like a solid oral opens up even more possibilities. But we need to do everything we can now given the huge potential for global obesity treatment for our medicines to play a key role in that and then ultimately impact hundreds of millions of people. So a lot of work to do here yet ahead. Thanks for the question.

### A - Joe Fletcher {BIO 23100909 <GO>}

Paul. Next question.

### Operator

The next question is from Laura Hanley from Berenberg. Laura, your line is live.

### Q - Laura {BIO 18877631 <GO>}

Hi, thanks for taking my question. And so, I think it's clear from your results that the mix shift to Mounjaro is rapidly in progress. But how should we think about the ex U.S. Trulicity contribution going forward, which did look weak this quarter? But at the moment, you're still supply restricted. Can we expect a return to growth into next year as constraints ease? Or should we now assume Trulicity is ex growth as you put the shift into Mounjaro? Thank you.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Laura, for the question. I'll hand over to Ilya Yuffa, President of Lilly International. Ilya, do you want to address Trulicity ex U.S. contributions in the quarter and going forward?

### A - Ilya Yuffa {BIO 21952737 <GO>}

Sure. First, thanks for the question. Listen, I think from a Trulicity standpoint, we had a healthy growth coming into later part of last year and we've been pretty transparent with both physicians as well as regulators that, due to tight supply we are encouraged not to start with new patients, we continue with that. To be transparent, because it's the right thing to do. And as we think about growth in incretin, we are looking as we build up capacity, as David mentioned, as we increase capacity both in the single use file and introduce Mounjaro in additional markets as we have in Australia, and we'll continue over the next number of weeks and months in other markets. And then transition towards a multi-use platform of clickpen in introducing Mounjaro. And so the overall growth in incretin will be mainly driven by as we are able to launch Mounjaro in new markets, that's probably where we'll get the growth. Thank you for the question.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Elliot. Paul, next question.

### Operator

The next question is coming from Umer Raffat from Evercore. Omar. Your line is live.

## Q - Umer Raffat {BIO 16743519 <GO>}

Hi guys, thanks for taking my question. I realize Mounjaro is not approved in obesity yet, but I'm just very curious how you are thinking about the pros and cons heading into that pricing decision, if there is any, because Novo does have that price premium, as you know on VigorOzempic. So on the one-hand, while Mounjaro price could be the same, because the dose is the same, but on the other hand, Novo has this dynamic where it can offer a lot more rebate for the obesity indication then you can if you leave the price unchanged. I'm just curious what your thought process is heading into that.

## A - Joe Fletcher {BIO 23100909 <GO>}

I'll hand over to Mike.

## A - Michael Mason {BIO 18347681 <GO>}

Yeah, thanks for the question. Obviously, we are not going to talk about price prior to approval. We're evaluating every scenario. We will make the right decision for patients who live with obesity. Thanks.

## A - Joe Fletcher {BIO 23100909 <GO>}

Paul. Next question.

## Operator

The next question is coming from David Risinger from Leerink. David, your line is live.



## Q - David Risinger {BIO 1504228 <GO>}

Yes, thanks very much, and thanks for all the updates today. So. At some major payors seem to under appreciate the broad health savings potential that incretins offer the non diabetic obese population and instead focus on criticizing drug pricing. So ahead of the results from Mounjaro's morbidity and mortality outcomes trial in 2027, how does Lilly plan to better inform payers about Mounjaro's health economics benefits in non diabetic obese patients? Thanks very much.

## A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Dave, for the question. Mike, do you want to talk a little bit about that about that. About the longer-term appreciation for the broader health benefits of medicine like tirzepatide?

## A - Michael Mason {BIO 18347681 <GO>}

Yeah. No, David, it's a good question, and one that we've obviously spent a ton of time on and done a lot of internal analysis and a lot of planning on. We will have a whole suite of real-world evidence and pragmatic trials so that we can answer this question clearly for payers and other stakeholders. In our conversations with payers, while they're concerned about the short-term budget impact, they do understand that losing weight will have benefits. It's not that hard of a sale because they do understand the benefits are intuitive.

If you look at the total number of like obesity rate of complications, there's over 200. And you look at some of these are just really devasting and very costly, like type 2 diabetes, coronary heart disease, hypertension, dyslipidemia. And then when you look at the cost of these on the U.S. alone, there's $370 billion in direct medical costs associated with obesity comorbidities and over $1 trillion in indirect annual cost. When payers see that people living with obesity and overweight drive 2.7x greater health care costs than normal individuals, that data does get their attention.

And so I think over time, we'll continue to provide health economic data. But also, I think the voice of those living with obesity will be very important in this. This is a disease that really materially impacts someone's both health and mental functioning, and is really important for people who live with obesity. Their goal is to lose weight and maintain that so they can help their long-term health benefits. And they're going to have a lot of voice in this. And I think both in commercial insurance as well as in states and in the federal government. And so I do -- I am confident over time that we will see increase in access. I think the most recent report shows that there's 50 million people in the U.S. that has access to obesity medication. So it will take time, but I think I do think more and more payers are appreciating the value that anti-obesity medications, especially when we get approval for tirzepatide will offer them.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thank you, Mike. Paul, next question.

### Operator

The next question is coming from Evan Seigerman from BMO Capital Markets. Evan, your line is live.

### Q - Evan Seigerman {BIO 18922817 <GO>}

Hi, thank you so much for giving me the question and congrats on the progress. So given the executive changes announced in October, how should we think about the direction of the immunology business now with Dan at the helm? Thank you guys.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Evan. Dave, do you want to take that?

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

Sure, I can start and let Dan come in. We've been really pleased with this business, which -- I think it's important to take the long view here. I mean I was involved in creating this like 10 years ago in both solanezumab and now mirikizumab, and hopefully soon lebrikizumab will form a really core portfolio for us, really exploiting ideas that we had some time ago. You know, what's next and you see here today advancing another checkpoint agonists into Phase II is a lot of decisions about, okay, what's next to take immunology to the next level. And that's largely going to be about key decisions, both internal portfolio and potentially externally, like with our DICE acquisition to find a new set of either single agent or combinations that can raise the standard of care in tough immunology diseases. Noting, in particular, in IBD and RA, the standard of care is hardly satisfied today. We measure a

pretty low performance stat as a success. So that's the mission that Dan, and we've hired Mark Genovese to the company and others, to really build the portfolio of the future. So I don't know, Dan, if you want to...

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

No, really excited about the opportunity. There's lots of work to do in immunology given the depth of unmet medical needs and the science is breaking here. So I hope we can continue to bring great drugs to market as we're doing with mirikizumab, and we hope to do with lebrikizumab soon and more to come.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Evan, for the question. Next question, Paul.

### Operator

The next question is coming from Chris Schott from JP Morgan. Chris, your line is live.

### Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks so much. Just as we're thinking about the upcoming tirzepatide obesity approval, just interested in your perspective of how we should anticipate commercial coverage ramping as we think of maybe the first couple of quarters post launch versus where it could be in a year or 2 from now? Just how quickly can we think about coverage coming on board? Thank you.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Chris. I'll hand over to Mike to comment on anticipation of commercial coverage over time. Mike?

### A - Michael Mason {BIO 18347681 <GO>}

Yeah. No, it's a good question. It will ramp up. We'll -- we're trying to be disciplined, and we're trying to make sure that we bring on access as quickly as is prudent. And so just like we did with Mounjaro, we'll take -- and make sure that we sometimes access has to materialize at an organic pace where it makes sense, and we'll make sure and use our judgment. So just like with Mounjaro, while we'd love to get out of the gate quickly, most importantly is a setup for long-term success. So you'll see kind of a natural ramp up that you would with any new product. And I think it's important, as you look in the first quarter of our launch last January, when you saw we go resupply, they were resupplying into a market where they already had capacity. So I think when you look at our access and you look at our volume as we head into next year, you'll see a ramp-up in volume as you see a ramp-up in our access. Thank you.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Mike. Paul, next question.

### Operator

The next question is from Steve Scala from TD Cowen. Steve, your line is live.

## Q - Steve Scala {BIO 1505201 <GO>}

Thank you very much. Question on why Lilly is evaluating higher doses of tirzepatide. There is risk in adverse event is uncovered and taints the franchise. And of course, there are IRA considerations. Does this suggest some reservation about the pipeline, either GGG or orforglipron, the former, which has safety signals, the latter of which took 5 years to get to Phase III? It would also be interesting to know whether it's the exact same molecule or it's been enhanced in some way. Thank you.

## A - Joe Fletcher {BIO 23100909 <GO>}

Thanks Steve for the question, Dan?

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

Okay. I'll take all of that. I think I'm not sure exactly what the safety signals you're referring to on retatrutide, I think -- but we're excited about both reta and orforglipron, which are both in Phase III and both advancing quickly. We've invested quite a lot in those Phase III programs, the robust cover multiple indications. So there's no hesitation or trepidation there at all. I think though not with any of those 2 molecules, which I expect to be great and important contributors to human health.

We have tirzepatide. I'm not exactly sure if we've maximized the dose response -- if we hit the flat part of the dose response curve yet. It looked like we might be close, but we want to explore it and so we're testing the higher doses in Phase II. I think we've had enough patients on this drug for long enough that I expect the risk of uncovering a new safety signal with sort of marginally higher doses is extremely low. So not worried about that at all.

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

Let me just jumping in here as we have questions like this. And you know we have a number of research projects in obesity and related mechanisms. And some people ask, well, how does this one effect that or whatever. That's not really the mindset in which we're pursuing this. We're -- we see ourselves as a leader in the space and have a unique opportunity. And our goal is to exploit every single idea until we get data that says we shouldn't. And so high dose tirzepatide is just another version of that, but it doesn't have a read-through to other things. We're just in all of the above mode in obesity.

## A - Joe Fletcher {BIO 23100909 <GO>}

Thank you. Paul, next question.

## Operator

The next question is from Chris Shibutani from Goldman Sachs. Chris, your line is live.

## Q - Chris Shibutani {BIO 3202082 <GO>}

Thank you and good morning. In about a week or so, we'll get detailed results from the select cardiovascular outcomes trial at the American Heart Meeting. Can you share with us what -- perhaps 3 key questions that the Lilly team will be looking at when we get detailed results?

### A - Joe Fletcher {BIO 23100909 <GO>}

Dan, do you want to weigh in on...

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

I don't know. I can start, maybe Mike has some to add here. Look, I'm excited to see that data, of course, as everyone else is, but the top line looked good. For me, I think we're sort of creating now data points on the line that connect the level of weight loss with the degree of cardiovascular benefit. I think this point fits on that line reasonably well. That in line which shows greater health benefits, including better -- fewer MACE outcomes, with greater degrees of weight loss, bodes very well for Mounjaro data given the very high degrees of weight loss that we saw in our trials. I'll leave it at that. See if Mike wants to add.

### A - Michael Mason {BIO 18347681 <GO>}

Probably the key question I'm looking at is like how much of the effect was driven by drug effect versus weight losses, probably the key question we're looking at.

### Q - Chris Shibutani {BIO 3202082 <GO>}

Thanks, Dan, and Mike.

### A - Joe Fletcher {BIO 23100909 <GO>}

Paul, next question.

### Operator

The next question is coming from Carter Gould from Barclays. Carter, your line is live.

### Q - Carter Gould {BIO 21330584 <GO>}

Great, good morning. Congrats on the progress. Maybe following on the prior question, but maybe more on sort of the impact of the flow data and your thoughts there, specifically you guys have taken sort of a different approach with your more recent assets there. In terms of targeting that population. Is Lily's view that those benefits will accrue to the class? And maybe just talk about how you think about targeting that segment down the road. Thank you.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Carter. For the question. Dan, do you want to comment on the flow data?

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

Yes. So you're asking about kidney disease. I mean I think the per fund effect that incretin seem to be having on the kidney is really a nice and important additive benefit here. This is something that's been observed with multiple class members now and expect it will extend into our incretins as well. So it's exciting, and I think proof that these drugs, perhaps in addition to the weight loss and when you seek control could have other direct metabolic benefits, including in the kidney.

### A - Joe Fletcher {BIO 23100909 <GO>}

Paul, next question.

### Operator

The next question is coming from Trung Hun from UBS. Trung, your line is live.

### Q - Trung Hun {BIO 22524697 <GO>}

Good morning all. Thanks for squeezing me in. Just one on Mounjaro U.S. pricing. So by our calculations, we think at 3Q '23, the net price is around $440 per Rx. For the rest of the year, do you think that net price can continue to go up and above the saving card price of $450? Are there payers willing to pay for this? Or is this broadly capped now until that saving card ends? And for next year, can you just give us your thoughts on if net price can meaningfully keep increasing? Thanks.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks. Trung. Mike, do you want to make any comments around Mounjaro pricing?

### A - Michael Mason {BIO 18347681 <GO>}

Yeah. No, I'd be happy to do that. I think maybe at a macro level, I would say that our gross to net for Mounjaro in Q3, kind of normalized. Before then, we had a number of saving card changes that made our gross in that rate dynamic. Our last and co-pay card change occurred late in Q2, so at the end of June. And so we -- Q3 was kind of a pure quarter where we didn't have any other co-pay card changes. And I would say that our Mounjaro rate normalized at that point.

Going forward, I think what you'll see is what you see normally out of -- for a product at this point in the life cycle, that as we pursue gaining access, there'll probably be some pricing pressure related to that. But we don't have any other co-pay card changes planned in the near future.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Mike. Paul, next question.

### Operator

The next question is coming from Robyn Karnauskas from Truist Securities. Robyn, your line is live.

## Q - Nicole {BIO 21224965 <GO>}

Good morning. Thanks for taking our question. This is Nicole on for Robyn. Just going back to obesity. How are you thinking through the impact on Mounjaro if IRA stays and (inaudible) and Ozempic prices decline in the 2026, 2027 time frame?

## A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Nicole for the question. I think it's if I heard you right, you're thinking about IRA impacts to maybe semaglutide and potential impacts to Mounjaro. Mike, do you want to comment on that briefly?

## A - Michael Mason {BIO 18347681 <GO>}

Yeah, no, I'm happy to do that. Obviously, it's too early to really impact how IRA will have an impact and the impact will have another product within the class. I think what's important for tirzepatide is it is the first dual-acting incretin. And we do think it has a unique profile. And in head-to-head results in type 2 diabetes that did show superior both A1c and weight to semaglutide. And so at the end of the day, I think the profile of the product will carry the day. And obviously, more to come on the RA as the first products go through the negotiation, we'll see the impact. But we're confident in the profile of tirzepatide.

## A - Joe Fletcher {BIO 23100909 <GO>}

Thank you, Mike. Paul, I think we have 2 calls left in the queue. Why don't we go through those 2 quickly, and then we'll wrap up.

## Operator

Certainly. The first one is a follow-up from Seamus Fernandez from Guggenheim. Seamus, your line is live.

## Q - Seamus Fernandez {BIO 7525186 <GO>}

Great. Thanks for the follow-up question. So just in terms of how you're thinking about the introduction of oral treatments and the importance of pushing for what would be hopefully a maintenance-type regimen. Is Lilly looking at oral therapies as more of a maintenance regimen opportunity? Or do you see a broader opportunity here, perhaps bringing in other mechanisms that perhaps could aid in pursuing, I guess, the ever-elusive metabolic set point? Thanks.

## A - Joe Fletcher {BIO 23100909 <GO>}

Yes, Dan, do you want to comment on that?

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

Yeah, thanks, Seamus. So maybe to Dave's previous answer, it's sort of an all of the above here. I think there's great opportunities on the oral as a stand-alone therapy for initiation of therapy. Also, yes, for maintenance therapy globally. And also, yes, for potential

combinations. I point out the obvious fact that this is a GLP-1 monotherapy. So we benchmark it against the best injectable GLP-1 monotherapy. But I don't expect, as an oral, it will achieve the same levels of X you can see with dual agonism like tirzepatide. So the future certainly will hold combinations like that.

### A - Joe Fletcher {BIO 23100909 <GO>}

Thank you. And last question, Paul, from the queue.



### Operator

Certainly, the last question will be a follow-up from Tim Anderson from Wolfe Research. Tim, your line is live.

### Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. What's the latest thinking on the topic of GIP agonism versus antagonism? So tirzepatide is the former, Amgen's drug is the latter. I've never seen 2 drugs in any category that have a similar clinical effect, but opposing underlying activity of the biologic target. Amgen says GIP antagonism is the way to go, supported by their genetic analysis. Whereas, Lilly think, have you looked similarly at genetic analyses to inform your view?

### A - Joe Fletcher {BIO 23100909 <GO>}

Thank you, Tim. For the last question, Dan.

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

Yeah, I'll take that. Of course, we have now, I think, more data on GIP agonism than anyone in the world and starting with tirzepatide, of course, which is a combo GLP-1, GIP agonist and head-to-head study against a pure GLP-1 agonist. And you can see some profoundly different effects here, looking at, for example, efficacy relative to tolerability. It looks like the GIP is boosting efficacy while also reducing the side effects that limit tolerability. So that was our initial evidence in human trials that involved - well, now tens of thousands of patients have been on tirzepatide in trials.

And then we went out to sort of prove this point by creating a pure GP1 agonist that just agonizes GIP to see what that could do alone. And again, we saw a very highly tolerated drug, consistent with what we understand about the mechanism of GLP-1 that probably could suppress actually nausea and vomiting that led to weight loss.

So I think human data trumps everything here, and we've got a ton of that. So we're pretty excited about GIP agonism. I can't really say what will happen with antagonism. But like you said, it's pretty unusual to have opposing mechanisms that both work in similar ways.



### A - Joe Fletcher {BIO 23100909 <GO>}

Thanks, Dan for the last one. Dave?

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

Okay. Thanks, Joe. We appreciate everyone's participation in today's earnings call and of course, your ongoing interest in Eli Lilly and Company. As I said, it's been a very productive year for Lilly so far, and we look forward to continuing this momentum through a busy end of year and fourth quarter.

So thanks for dialing in today. Please follow up with the IR team if you have questions we did not address on the call. And hope everyone has a great rest of the week and rest of the day today. Take care.



## Operator

Thank you. And ladies and gentlemen, this does conclude our conference for today. This conference will be made available for replay beginning at 1:00 p.m. today running through December 7 at midnight. You may access the replay system at any time by dialing 800-332-6854 and entering the access code 544467. International dialers can call (973) 528-0005. Thank you for your participation. You may now disconnect your lines.