Q2 2022 Earnings Call

Company Participants

- Anat Ashkenazi, Chief Financial Officer
- Anne White, Senior Vice President and President
- Dan Skovronsky, Chief Scientific and Medical Officer
- Dave Ricks, Chairman and Chief Executive Officer
- Ilya Yuffa, Senior Vice President and President
- Jacob Van Naarden, Senior Vice President and Chief Executive Officer
- Kevin Hern, Vice President of Investor Relations
- Mike Mason, Senior Vice President and President

Other Participants

- Andrew Baum, Analyst
- Carter Gould, Analyst
- Chris Schott, Analyst
- Chris Shibutani, Analyst
- Colin Bristow, Analyst
- David Risinger, Analyst
- Evan Seigerman, Analyst
- Geoff Meacham, Analyst
- Kerry Holford, Analyst
- Louise Chen, Analyst
- Mohit Bansal, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst

Presentation

Operator

And ladies and gentlemen, thank you for standing by. Welcome to the Lilly Q2 2022 Earnings Conference Call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session and instructions will be given at that time (Operator Instructions) And as a reminder, your conference is being recorded. I would now like to turn the conference over to your host, Kevin Hern, Vice President of Investor Relations. Please go ahead.

Kevin Hern {BIO 20557573 <GO>}

Thank you. Good morning, everyone and thank you for joining us for Eli Lilly and Company's Q2 2022 Earnings Call. Apologies for the hour delay, we had some technical issues on AT&T side. So thanks for your patience.

I'm Kevin Hern, Vice President of Investor Relations. Joining me on today's call are Dave Ricks, Lilly's Chair and CEO and 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; Jacob Van Naarden, CEO of Loxo at 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 of the Investor Relations team as well as Joe Fletcher, who will be taking over leadership of the IR team this month.

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 three. 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 is 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 the call over to Dave.

Dave Ricks {BIO 16504838 <GO>}

Thanks a lot Kevin. In Q2, we achieved a number of impactful pipeline milestones including approval and launch of Mounjaro in the US, the FDA submission and acceptance of donanemab as well as pirtobrutinib and positive top line results for lebrikizumab and EU in Japan submissions for mirikizumab. This pipeline progress underscores the breadth and depth of our exciting long-term outlook. Perhaps the headline story for Lilly the second quarter was the launch of Mounjaro in US where initial uptake has been strong. We're hearing a great deal of enthusiasm from the field and we're excited about the potential for this new medicine to provide A1c and weight loss benefits to adults living with type two diabetes. We remain focused on gaining broad open access for Mounjaro and expect the full impact of this medicine for patients and our business to be realized over time as that access is achieved.

Turning to Q2 financial results and progress on our strategic deliverables, we saw a relatively flat top line performance in constant currency. As strong volume driven growth for key products like Verzenio Jardiance and Trulicity was offset by lower prices for -- as well as for Alimta's patent expiry in key markets around the world and last year's sale of Cialis rights in China. Volume for this quarter grew a robust 10% when excluding revenue from Alimta, the sale of Cialis rights in China and COVID 19 antibodies, revenue grew 6% compared to Q2 2021. In Q2, our newer medicines contributed 18% to volume growth and

now account for 67% of our core business revenue, which we believe, together with a robust pipeline is the most important indicator of the strength and durability of our growth outlook. Our non-GAAP gross margin was 79.8% in Q2, an increase of approximately 50 basis points compared to the prior year. Our non-GAAP operating margin was 20.5%, which includes a negative impact of approximately 680 basis points attributed to acquired in-process R&D and development milestone charges. At our investment community meeting in December, we outlined five potential new medicines that could launch over the next two years, which could service as catalyst to driving top tier growth through the decade. There have been important pipeline development since our Q1 earnings call for all five including the US approval and launch of Mounjaro and type 2 diabetes and a positive CHMP opinion in the European Union. FDA acceptance and Priority Review designation for donanemab in early symptomatic Alzheimer's disease.

FDA acceptance and Priority Review designation for pirtobrutinib in mantle cell lymphoma for patients previously treated with a BTK inhibitor. Submissions for mirikizumab and ulcerative colitis in the EU and in Japan. Positive top-line 52-week data for lebrikizumab in moderate to severe atopic dermatitis and we also announced US, EU and Japan regulatory approval for Olumiant in alopecia areata. Last month, we announced plans for a $2.1 billion investment in two new manufacturing sites here in Indiana to support increasing demand for existing products as well as demand for potential new medicines in our pipeline. This announcement followed Lilly's recent investments in new facilities in Massachusetts, North Carolina and Ireland and will further expand Lilly's manufacturing network for active ingredients and new therapeutic modalities such as genetic medicines.

These investments underscore our confidence in the growth of our portfolio in the Company. Finally, we distributed nearly $900 million in dividends to our shareholders in Q2. On slide five, you'll see a list of key events since our Q1 earnings call including several important regulatory clinical and COVID-19 antibody updates. As previously announced in Q2, we entered into an agreement with the US Government to supply 150,000 doses of bebtelovimab for approximately $275 million, in an ongoing effort to provide COVID-19 treatment options for patients. Doses of bebtelovimab valued at approximately $130 million were shipped in Q2 and the remainder of that order will ship in Q3.

Today we are announcing that in collaboration with the US government, we intend to begin making bebtelovimab available for purchase by states, hospitals and certain other providers through a sole distributor agreement. This will happen later this month, which is prior to the anticipated depletion of the US government's currently available supply. As we move from large ad hoc federal government purchases, the sales and distribution of COVID-19 antibodies to a broader set of purchasers, we will now integrate estimated sales into our forward guidance. As we've said previously, we don't see COVID-19 antibodies as a major long-term driver of growth for the Company. Nevertheless, we will continue to do our part where we can to help fight the COVID-19 pandemic with the last monoclonal antibody treatment standing that neutralizes against Omicron variant.

And now I'll turn the call over to Anat for a more detailed review of our Q2 results.

Anat Ashkenazi {BIO 19888043 <GO>}

Thanks, Dave. Slide 6 summarize it. (technical difficulty) Slide six summarizes financial performance in the second quarter of 2022, I'll focus my comments on non-GAAP performance. We had a few notable items impacting the year-over-year financial comparisons. Foreign exchange rates had roughly 300 basis point impact on revenue this quarter, as we saw Q2 revenue declined 4% or 1% on a constant currency basis. In Q2 of 2021, we sold our rights to Cialis in China resulted in a $170 million of one-time revenue impact, and this quarter we also saw the full impact of the loss of exclusivity for Alimta in Europe and Japan, and have started to see the impact of multiple generic entrants in the US.

When excluding revenue (technical difficulty) Hopefully everyone (technical difficulty) Okay. I'll continue and hopefully everyone can hear. (technical difficulty) When excluding revenue from Alimta, the sales of Cialis rights in China (technical difficulty) Thank you. Hopefully, you heard, I will repeat my less sentence, so when excluding revenue from Alimta, the sales of Cialis rights in China in Q2 of last year and COVID antibody, total revenue grew 6% highlighting the solid momentum for our core business in the second quarter. We expect that this growth rate will accelerate in the second half of the year. Moving on to gross margin as a percent of revenue increased 50 basis points to 79.8% in Q2 of 2022. This increase in gross margin was primarily driven by product mix and the favorable effect of foreign exchange rates on international inventories sold, partially offset by lower realized prices. Increase in logistics and manufacturing costs due to inflation had a modest negative impact on gross margins in Q2.

Total operating expenses increased 14% this quarter, which as discussed on our Q1 earnings call are now inclusive of acquired in-process R&D and development milestone charges following guidance from the SEC. Acquired IPR&D and development milestone charges represented nearly 1,200 basis point of the Q2 OpEx growth. Marketing, selling and administrative expenses decreased 4%, driven mostly by the favorable impact of foreign exchange rates. R&D expenses increased 8% driven by higher development expenses for late-stage assets partially offset by lower development expenses for COVID-19 antibodies. This quarter, we recognized acquired IPR&D and development milestone charges of $440 million or $0.46 of EPS, primarily related to a charge associated with the buy-out of substantially all future obligations that were contingent upon the development, regulatory and commercial success of our mutant-selective PI3k alpha inhibitor.

In Q2 2021, acquired IPR&D and development milestone charges were $43 million or $0.04 of EPS. Operating income decreased 32% in Q2, primarily due to higher acquired IPR&D and development milestone charges. Operating income as a percent of revenue was 20.5%, which includes the negative impact of approximately 680 basis points attributed to these charges. Other income and expense of approximately $13 million this quarter compared with income of $5 million in Q2 of 2021. Our Q2 effective tax rate was 14.2%, a decrease of 10 basis points compared to the same period in 2021. This decrease was driven by favorable tax impact related to the implementation of the provision of the 2017 Tax Act related to the capitalization of R&D expenses, offset by the tax of not -- tax impact of non-deductible development milestone. At the bottom line, earnings per share declined 32% this quarter to $1.25 per share. The most significant driver of the year-over-year decline was the impact of acquired IPR&D and development milestone charges which had $0.46 negative impact in Q2 of this year compared to $0.04 in Q2 of last year.

On Slide eight, we quantify the effect of price, rate and volume on revenue growth. This quarter, US revenue grew 6%. Excluding revenue from Alimta, which declined significantly due to broad generic entry in May and COVID-19 antibodies, revenue grew 11% in the US. This volume-driven growth was led by Trulicity, Verzenio and Jardiance. We experienced a net price decline of 8% for Q2 driven by lower realized prices for Humalog, Alimta and Forteo, due to higher rebated segments making slightly larger portion of the business, higher contracted rates and the list price reduction for Insulin Lispro injection this year.

Lower realized prices for Taltz were also a driver due to the impact of changes to estimates for rebates and discounts, largely driven by favorable adjustment in the base period and to a lesser extent continued pull-through of existing access. For the first half of 2022, net price decline in the US was 4% and we continue to expect mid-single digit net price decline for the full year. Moving to Europe. Revenue in Q2 grew 1% in constant currency. Excluding revenue from Alimta, which loss exclusivity in June of 2021 revenue grew 12% in constant currency driven primarily by volume growth for Trulicity, Jardiance, Taltz and Verzenio. For Japan Q2 revenue decreased 22% in constant currency as our business there continues to be negatively affected by significant declines in off patent products primarily Cymbalta and Alimta, which both faced generic entry beginning in June 2021. Key growth products represented 69% of total revenue in Japan and grew 11% in Q2 on a constant currency basis. We continue to expect to return to growth in Japan beginning in 2023. In China, revenue declined 32% in constant currency driven by the impact of the NRDL formulary access resulting in lower realized prices, partially offset by increased volume for certain new products including Verzenio, Tyvyt, Trulicity and Taltz. We also experienced a price decline for Humalog, due to the impact of volume based procurement. We expect improved access to continue to drive future volume growth more than offsetting the price decline over time. With the latest COVID-19 outbreaks in China and the subsequent protective measures intended to control the spread of the virus, we have seen lower volumes than we otherwise would have expected in Q2, particularly for infused products. For Tyvyt, we are also seeing the impact of increased competitive pressures. Revenue in the rest of the world increased 3% in constant currency, primarily driven by increased sales of key growth products. For the full year, we continue to expect mid-single digit net price decline in each of the US, EU and Japan, and a double-digit price decline in China, resulting in a worldwide net price decline in the high single digits. As shown on slide nine, our key growth products continue to drive robust worldwide volume growth. These products drove 18 percentage point of volume growth this quarter and continue to underpin our overall performance and outlook.

Slide 10 further highlights the contribution of our key growth products. This quarter these brands grew 20% or nearly 24% in constant currency, generating $4.3 billion in sales and making up 67% of our core business revenue. We continue to see further growth opportunities for these products. For example, we are extremely pleased to see the strong trajectory of Verzenio driven by the adjuvant indication, including recent acceleration in new to brand share of market. In the injectable incretin market, we see significant opportunity for further class growth, as these medicine currently make up only 25% of total prescription in the US branded diabetes market and have the prospect of expanding the market through the earlier usage for glucose control and weight loss in the treatment of type 2 diabetes.

Trulicity is experiencing accelerated demand in many international markets due to market growth and the limited availability of competitor GLP in select markets. We are working to meet this increased demand while also implementing actions in select countries to manage growth and minimize patient impact. This outlook for Trulicity is included in our guidance. Lilly is thrilled to have both Trulicity which has the longest length of therapy of any GLP-1 and Mounjaro which could offer step change in innovation for the treatment of type 2 diabetes and other metabolic indications as option in this class of medicines. Given the excitement and significant interest with the FDA approval of Mounjaro for type 2 diabetes, I'd like to briefly provide an update on what we're seeing and hearing in terms of early launch. After US approval in mid-May, our full-scale launch began in mid-June.

Our commercial team is prepared, energized and observing a high level of engagement across channels as we rollout a patient-centric approach to launching Mounjaro for patients with type 2 diabetes. The financial results you see for Mounjaro today reflect significant utilization of samples were accepted and co-pay assistance program to get patients off to a strong start. Payer negotiations are progressing as expected and we're taking a disciplined approach to establish Mounjaro's access and our focus on delivering the same broad open access, which we achieved for Trulicity. As we remain focused on strong execution, we're encouraged by the prescription trends from Mounjaro including the most recent IQVIA data showing over 20% share of market for new-to-brand prescriptions in the type 2 diabetes injectable incretin plus.

We are also pleased to see the total Lilly new to brand sharing the type 2 diabetes injectable incretin class has grown nearly 12 percentage point since the launch of Mounjaro. Given the heavy utilization of co-pay cards as we build out access for Mounjaro, prescription trends will likely provide a more accurate measure of launch uptake, the net sales over the next few quarters. We are pleased with the initial uptake of Mounjaro which is at the high end of our contemplated scenarios. We do not anticipate supply constraints for the US launch of Mounjaro and we will monitor US uptake to determine the appropriate timing for OUS launches. As a reminder, over the last several years, we have made significant investments to grow our global manufacturing capacity to support Mounjaro volume including our new RTP site in North Carolina, which will come online in 2023.

On Slide 12, we provide an update on capital allocation. For the first half of the year, we invested $4.5 billion to drive our future growth through a combination of R&D expenditures, business development outlays and capital investments. In addition, we returned approximately $1.8 billion to shareholders in dividends and repurchased $1.5 billion in stock. Our capital allocation priorities remain consistent as we continue to fund our key marketed products and expected new launches, invest in our pipeline, pursue opportunities for external innovation to augment our future growth prospects and return excess capital to shareholders.

Slide 13 is our updated 2022 financial guidance. Our full year revenue outlook is unchanged. It now includes an additional $400 million of headwind from foreign exchange rates since our previous guidance update for a total impact of roughly $700 million of FX headwind for the full year compared with our original guidance. This incremental headwind is offset by additional forecasted revenue from our COVID-19

antibodies bebtelovimab which includes $275 million from the US government agreement announced in June of this year, as well as estimated revenue from the inception of non-US government distribution that Dave mentioned earlier.

As we look ahead, Q3 will mark the first full quarter impact of Alimta US patent expiry. In addition Q3 of 2021 revenue benefited from Olumiant COVID-19 sales that will provide roughly 2.5 percentage points of headwind to our top line growth in the quarter. Our outlook for gross margin, SG&A and research and development remains unchanged. While the range is unchanged, SG&A does include additional commercial investments for selected key growth products in the second half of the year. Our guidance now include acquired IPR&D and development milestone charges of approximately $610 million reflecting total charges in the first half of the year. We have had no material acquired IPR&D or development milestone charges at this point in Q3 and this guidance does not include any impact from potential or pending business development transactions in the second half of the year. GAAP and non-GAAP operating margin decreased 100 basis points to approximately 27% and 29% respectively, primarily due to the negative impact attributable to foreign exchange rates and acquired IPR&D and development milestone charges to-date. Our non-GAAP range for other income and expense remains unchanged.

On a reported basis, other income and expense is now expected to be expense in the range of $500 million to $600 million reflecting the impact of net losses on investments in equity securities during the second quarter. Our tax rate and EPS in the first half of the year still includes the favorable impact of the provision in the 2017 Tax Act that requires capitalization of research and development expenses for tax purposes. Our financial guidance for the full year assumes this provision will be deferred or repealed by Congress effective for 2022. If this provision is not deferred or repealed effective this year, then we would expect a reported and non-GAAP tax rate to be approximately 10% to 11%. Based on these changes, we have lowered our reported EPS guidance by $0.34 to now be in the range of $6.96 to $7.11 per share and lowered our non-GAAP EPS guidance by $0.25 to be in the range of $7.90 to $8.05. The $0.25 reduction or non-GAAP EPS range is driven entirely by the impact of foreign exchange rates as the impact of EPS of acquired IPR&D and development milestone charges for selected -- in selected products are offset by the impact of additional sales of bebtelovimab.

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

Dan Skovronsky {BIO 15349505 <GO>}

Thanks, Anat. Looking across Lilly R&D, I continue to be quite encouraged by the potential we have to turn cutting edge science into life changing medicines for patients. This potential is becoming a reality in the late stage portfolio, where I'll focus my remarks today, but also it's becoming more and more evident in our earlier-stage projects. And I look forward to providing updates on some of these assets in future quarters. Given updates we provided at ADA in June, including detailed results from SURMOUNT-1, I'll focus today's R&D update on the late stage progress since our last earnings call more generally.

Slide 14 shows select pipeline opportunities as of August 1 and slide 15 shows potential key events for the year, I'll cover both of these slides by therapeutic area. Starting with immunology. Along with our partner Incyte, we're proud that Olumiant has now been approved as a first-in-disease systemic treatment for adults with severe alopecia areata in the US, EU and Japan. Alopecia areata, is a significant unmet medical need and we're delighted about what this medicine could mean for people living with this disease. We also announced top line data for the lebrikizumab Phase 3 monotherapy maintenance studies in patients with moderate to severe atopic dermatitis, which showed 80% of lebrikizumab responders maintained improvements in skin clearance and disease severity at 52 weeks. Data supported both once every two week and once every four-week maintenance dosing with consistent and durable responses.

We believe the potential for a once every four-week maintenance dosing regimen could be an important point of differentiation for patients and healthcare providers. Lilly is planning submission of lebrikizumab to the FDA in 2022 followed by submissions to other regulatory agencies around the world. Almirall has rights to develop and commercialize lebrikizumab for atopic dermatitis in Europe and is planning for submission to the EMA in 2022. Shifting to mirikizumab, we presented results from the Phase 3 maintenance study LUCENT-2 at the DDW meeting. This study showed that for patients who responded to treatment on mirikizumab in the 12 week induction period, 50% of patients who received mirikizumab maintenance therapy achieved clinical remission at one year compared to one-fourth of patients randomized to placebo.

In addition to the US regulatory submission of mirikizumab for ulcerative colitis that we announced earlier this year, we have now submitted in the EU and Japan. Also noted here in immunology is a Phase 2 start for a BTLA agonist antibody in SLE and our new KB1.3 inhibitor shown in Phase 1. Our IL-2 conjugate is now listed under its nonproprietary name respac aldesleukin [ph]. Moving to diabetes, we're thrilled that Mounjaro is now approved in the US, is the first and only GIP and GLP-1 receptor agonist for the treatment of adults with type 2 diabetes.

We're pleased to have received a positive CHMP opinion in the European Union and we're hopeful for full approval by the EMA later this quarter. We presented the exciting detailed results from SURMOUNT-1 evaluating tirzepatide for treatment of weight management in participants with obesity or overweight at ADA with simultaneous publication in the New England Journal of Medicine. New data include an exploratory analysis that showed roughly 40% of patients achieved at least 25% weight reduction on the 15 milligram dose compared to less than 1% of patients on placebo.

Additionally, we saw meaningful reductions in blood pressure and lipids, as well as reduction in fat mass that was nearly three times greater than that in lean mass. Encouraging data also showed that for those patients who had pre-diabetes at the start of the study, over 95% returned to normal glucose levels. The efficacy, safety and tolerability data in SURMOUNT-1 exceed our expectations. Based on our existing robust dataset for tirzepatide, we've now engaged with the FDA and we'll have a meeting soon to evaluate whether there is a potential path forward to registration for chronic weight management based on SURMOUNT-1 combined with data from the SURPASS program.

We'll continue to communicate to investors as their material updates. We continue to expand our clinical program for tirzepatide and we've now initiated our Phase 3 study evaluating tirzepatide for treatment of obstructive sleep apnea. We also have become a new -- we also have begun a new trial called SURPASS EARLY [ph], which evaluates the long-term safety and efficacy of tirzepatide compared to standard of care when initiated early in the course of type 2 diabetes. Later this year, we'll begin SURMOUNT-5, a head to head study comparing weight reduction for tirzepatide versus semaglutide 2.4 milligrams.

And finally, later this year, we expect to initiate SURMOUNT MMO, our Phase 3 morbidity and mortality in obesity study. Moving to our weekly basal insulin FC also known as BIF. We've now initiated a second Phase 3 trial QWINT-2 which is evaluating BIF compared to degludec in adults with type 2 diabetes who are starting basal insulin for the first time.

Our Phase 2 GGG tri agonist is now listed under its nonproprietary name Retatrutide. Also in this area, two assets have now entered Phase 1 clinical development, our dual amylin calcitonin receptor agonist or DACRA and our PNP LE3 [ph] SI RNA.

In oncology, we are announcing today that the FDA has accepted the filing for pirtobrutinib in mantle cell lymphoma for patients previously treated with a BTK inhibitor with priority review designation under the accelerated approval pathway. Improved treatment options are needed for this challenging disease and we're encouraged that this potential new medicine could be available to patients in early 2023. In early phase oncology, we've moved our mutant selective PI3 kinase alpha inhibitor into Phase 1 development. And finally moving to neuroscience. We're also pleased to announce the FDA has accepted the filing for donanemab for the treatment of early symptomatic Alzheimer's disease and is granted priority review designation under an accelerated approval pathway. We continue to look forward to the top line results of the Phase 3 confirmatory study TRAILBLAZER-ALZ 2 by mid 2023 which if positive will form the basis of our application for traditional regulatory approval. You also notice, we're now referring to N3pG4 by its nonproprietary name Rumtunatug [ph].

We plan to initiate the Phase 3 program for Rumtunatug in the coming weeks. As you can see, Q2 was another productive quarter for pipeline advancement at Lilly. Now I'll turn the call back to Dave for closing remarks.

Dave Ricks {BIO 16504838 <GO>}

Thanks, Dan. Before we go to Q&A. Let me briefly sum up the progress we've made in the second quarter. We're encouraged by the performance of our key growth products, which now represent 67% of our core business. We expect to see this grow over time as we work to launch more innovative medicines like Mounjaro. Excluding the impact of acquired IPR&D and development milestone charges, we expect to see operating margin expansion from both revenue growth and driving further efficiencies in our business. We saw significant progress in our pipeline this quarter with the approvals of Mounjaro in type 2 diabetes and Olumiant in alopecia areata. We also saw progress on our next wave of potential growth catalyst with the FDA acceptance of donanemab as well as pirtobrutinib in -- and positive top-line readout for lebrikizumab and additional submissions for mirikizumab.

Finally we returned $900 million to shareholders via the dividend and share repurchases. Looking to the future, we are confident in our long-term growth prospects as we are focused on developing groundbreaking therapies in areas of significant unmet need as well as driving exceptional execution for our recently launched medicines, so they reach patients, who need them. Before we close, I'd like to comment as well, this is Kevin Hern's last call as Head of our IR team. And before I turn the call over to him to moderate the Q&A session, I'd just like to thank him on behalf of our shareholders, our Board and of course our executive team and employees. He has done an outstanding job for the last four and half years, strengthening our relationships with the Street as well as being an ambassador to both convey the Company's messages to shareholders but also inform management about shareholder perspectives. We wish him the best in his new assignment, transitioning to a leadership role in our US commercial group.

Now, I'll turn the call over to Kevin for his last Q&A session.

Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Thanks for those kind words, I will definitely miss this. We'd like to take questions from as many callers as possible, so please limit your questions to two per caller. Luis, if you can provide the instructions for the Q&A session. And then we're ready for the first caller.

Questions And Answers

Operator

Thank you (Operator Instruction) The first question will come from the line of Geoff Meacham from Bank of America. Please go ahead.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey, guys. Thanks so much for the question. Just have two quick ones. One on Mounjaro, I know it's pretty early in adoption, but maybe just talk about the source of new starts meaning are they GLP-naive or experience and then talk about the expected payer dynamics looking to 2023. And for Dan on tirzepatide, I know your regulatory discussions are ongoing in obesity. But do you think, you can also use the safety database from diabetes and other indications, when you look kind of NASH sleep apnea et cetera. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Geoff. We'll start off with Mike on Mounjaro. And then, Dan, if you want to comment on regulatory for tirzepatide obesity. Mike?

A - Mike Mason {BIO 18347681 <GO>}

Yeah, thanks, Geoff. Thanks for the question. What we've seen -- first of all, we're incredibly excited about the very robust launch we've had with Mounjaro. We're also excited about the source of business that we're seeing. 72% of Mounjaro is coming from new patients into the incretin class. We think that's very important -- important for accelerating class

growth and we have seen class growth both at total prescriptions, new-to-brand and MTS accelerate since Mounjaro's launch. Of the 28% of the volume that's coming from switches, only 30% of that is from Trulicity and 70% is from other GLPs. And so as a result, as Anat indicated in earlier, we're actually seeing Lilly incretin share market growing, which is the sign that we -- of a robust solid foundation that we're laying and so MBRX have increased -- our share by -- the Lilly share in the injectable market by 12% and new to treatment starts by 10%.

So we're very happy. We're growing the class and the market share at the same time. Your second question around payer dynamics, it's going as expected for us. We're trying to stay very disciplined. I think our focus is to set ourselves up for long-term success not short-term success. And that's what we're doing. So it's going as expected. So far we have both commercial and Part D form access on Express Scripts, Cigna and Humana formularies.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Dan?

A - Dan Skovronsky {BIO 15349505 <GO>}

Yeah, thanks, Geoff for the question. You're pointing out that correctly that we intend to pursue a number of related indications for tirzepatide. Some of them have overlapping patient populations. Most of the indications we pursue have a base of patients that either have obesity as a pre-existing and sometimes causative condition such as obstructive sleep apnea or heart failure in people with obesity. Other indications, might be a mix of type 2 diabetes and obesity representing a large number of patients, such as NASH. So where applicable, safety exposures from similar properties, it can be used to support a -- submissions. Of course some of those programs are staggered in time and so by the time we get efficacy data, those indications will also have quite likely the rest of the SURMOUNT program, but where we are today is quite a large and robust safety database from the entire SURPASS program as well as SURMOUNT-1.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Geoff, thanks for your questions. Next caller, please.

Operator

The next caller is Chris Schott from JPMorgan. Please go ahead.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks so much for the questions, just two from me. I guess just on the obesity opportunity, I guess that the feedback you've been getting on that SURMOUNT data, I guess is there any change in terms of how you anticipate payers will approach obesity? I guess the heart of the question is, do you anticipate, we're going to really need to see some of the CV morbidity-mortality data before we can think about broad coverage for obesity medications? Are you seeing payers potentially more interested in covering these type of products given some of the profile that kind of emerged from that study.

My second question was one for Dave, I guess on -- just on healthcare reform, I know you love answering these questions, but I guess, as you've just been so involved in this process, or just appreciate your thoughts on the latest bill we're seeing and just kind of the impact you'd expect it to have on the industry and maybe Lilly more specifically? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Chris. We'll go to Mike first and then on obesity and then Dave for healthcare reform.

A - Mike Mason {BIO 18347681 <GO>}

Yeah, great question. The SURMOUNT-1 data was phenomenal data for for patients and physicians who treat obesity. We -- I think there is a combination of effects that will effect employers and the government to increase access for obesity agents. One is the data we produce, and I think obviously, the first data we're producing is the -- is the weight loss, as well as the factors like lipids and blood pressure and the data we produced so far has been stellar. So I think, the better data we produce in SURMOUNT-1 through SURMOUNT-4 is just going to help us in the short term. Long term, we think there's a lot of comorbid conditions associated with obesity like CV and heart failure and sleep apnea and the better data that we, that we support there will open up those indications, where -- are highly -- have a lot of overlap with obesity. And so we're excited about those trials and seeing those data as those trials complete.

And then lastly, the more we can drive consumer interest in this that that puts pressure on employers and the government to be able to gain access for this. And so I think, we're -- we've got strong plans on all three fronts. And we're excited about the first data disclosure we've had on obesity. So we're very bullish on the long-term prospects of the obesity market and treat appetite dwell [ph] on it.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Dave?

A - Dave Ricks {BIO 16504838 <GO>}

Yeah, Chris. Thanks for the question. I think everybody probably on the call has a good grasp of what's in this package, difficult to speculate on probabilities but certainly a lot higher than a month ago that something crosses the line. There may be some adjustments to this as they go through that rudimentary [ph] process and whatever changes might occur still to come in the Senate and the House. But if -- what we're looking at passes maybe that's your question. As you know, we've been for the Part D reforms. I think they're good incremental changes particularly capping out-of-pocket and getting rid of the donut hole concept. Unfortunately they don't improve the concept of facing patient cost sharing on net pricing, which we were hoping it would, but by itself, we would support that.

The CPI adjustment is not really an issue, as probably everyone on this call knows. There's already lots of CPI capping that goes on in the commercial marketplace and with CPI being where it is now, as well, I think list prices in the drug business are not nearly as fast as the rest of the economy, but the negotiation piece is a problem. And I think, in the short

term, speaking for our company, but probably the industry. It doesn't do much. They don't really start until '26 anyway, but yeah, in the mid term, there'll be of course some products that will have attenuated lifecycles. And I think, that will cause some headwinds for the industry and we'll see if any Lilly products get caught up in that, but probably to me the most damaging thing about it is, it sends a signal to investors and capital allocators like us that small molecules and particularly small molecules in diseases that require stepwise development like cancer, where we start in stage and later stages and work our way to adjuvant or even in some orphan conditions really aren't wanted and are worse or lot less.

So we will focus our resources on other areas of innovation. We got plenty of those. And so with the rest of the sector and I think that's really a miss for the patients that probably want better oral cancer drugs in the future and an orphan disease drug. So I think, that's probably not being talked about enough and I just wanted to emphasize that.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Chris. Thanks for your questions. Next caller, please.

Operator

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

Q - Seamus Fernandez {BIO 7525186 <GO>}

Well. Great, thanks for -- thanks for the question. So just a couple of questions here. Dave, I was just hoping to get a little bit more color on the comment that you made there with regard to orals, how do you see that impacting your efforts to bring forward oral diabetes drugs and is it more a benefit to complex oral therapies that aren't small molecule per se, but perhaps some more peptide-oriented.

I know you guys are working on some efforts along those lines. So just interested to know if the legislation would imply that as well in the small molecule perspective, we see a number of oral GLP-1 seeking to come to market at some point in time. And then separately, just on. Dan, on the glucagon mechanism. I see GGG listed in two Phase 2 clinical trials but Mazditide [ph] your (inaudible) product is listed just in sort of the Phase 1 in diabetes. I'm wondering if you guys have officially made a decision to move forward with GGG or if Mazditide is still potentially in the mix of kind of your next-gen assets in the obesity space? Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Seamus. We'll go to Dave and then, Dan.

A - Dave Ricks {BIO 16504838 <GO>}

Yeah. Thanks, Seamus. I mean, I guess put a finer point on it. Each project will have to be evaluated one by one. But I think you will probably see 10 years down the line fewer small molecule oral products developed in the industry than would have been otherwise the case if this bill passes. Again that to me is the miss, and I think it -- there is still probably quite a bit of advantage in oral small molecules in sort of large primary care indications,

especially if in the case of like GLP, we could accept that weight loss will provide broader benefits for the earlier question about when sort of the -- the belief system tips over and people just accept chronic weight management is good for health like reduce blood pressure, is good for cardiovascular risk. And I think those products will be evaluated one by one and big opportunities, I think will advance and do well. They will have a 10-year weighted [ph] life cycle in the government business and that will have to be factored in.

But we'll look at that. What I was referring to is more, I think in narrower revenue opportunities. It just gets a lot harder and when by kind of construct, your new indications can't be compressed forward because of the way we develop drugs in some of these diseases. That's a problem. And I don't think that was well thought through. And there will be a long-term implication to that. One other thing, I probably should say is this bill raises $300 billion for the federal government off the back of the industry probably cost the industry at least $1.5 trillion and only about $50 billion of that like 10% is going back to patient benefit support.

And I think that's another tenant when we were leading pharma at Lilly was to make sure, whatever came out in the industry went back to patients. That's not happening here and that needs to be discussed as well.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Dan?

A - Dan Skovronsky {BIO 15349505 <GO>}

Yes, thanks Seamus for the question on our glucagon containing molecules. We previously said that we have two, in clinical development. Mazditide [ph] which is our oxyntomodulin that's glucagon plus GLP-1 and Retatrutide, which is our GGG which is glucagon GLP-1 and GIP-1, you're right that the GGG molecule is ahead in development that's in Phase 2 and the oxyntomodulin still in Phase 1, I think they're both viable as next-generation weight loss products, but to be clear here, it's a very high bar. We're looking for a major step change above the really remarkable results we saw in SURMOUNT-1. I think they both have that potential, but we're going to need to see more data to know which if either goes forward to Phase 3, just like when we are doing Phase 2 in tirzepatide, which is just a few years ago, we noted that it had to have a step-change to go forward to Phase 3, if you hear us talking about when are -- growth of these molecules going to Phase 3, it's [ph], we saw that kind of a big step change.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Seamus, thanks for your questions. Next caller, please.

Operator

The next caller is Louise Chen with Cantor. Please go ahead.

Q - Louise Chen {BIO 21301405 <GO>}

Hi, thanks for taking my questions. So my first question for you was on the obesity product. Do you see any potential read-throughs from Novo Select study tirzepatide and have you given any color on how you want to structure your studies on an outcome basis for obesity? And then secondly, you've been quiet on the Alzheimer's front, but just curious, if you have any updated thoughts on the market opportunity for donanemab especially in front of some of these Phase 3 trials will read out at the end of the year? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Louise. We'll go to Dan for the question on the Select trial and then Anne for the question on Alzheimer's?

A - Dave Ricks {BIO 16504838 <GO>}

Hi, Louise. Thanks for that question. Of course, we always root for our competitor's success on clinical trials. We want great data so that we can have great drugs to help patients. I think they -- Novo announcing that they pass the interim analysis but didn't stop the trial for efficacy, is fine. I think there is really pretty significant differences here between tirzepatide and semaglutide that we just have to remember the different mechanism, the different degree of efficacy on various outcomes, different trial designs, different populations to some extent. So we don't change our design of our SURMOUNT MMO study. We don't change our thinking about probability of success. As Mike said earlier, we are highly confident in this mechanism based on all of the data that we've seen. Of course, starting with the quite dramatic weight loss, which should be a benefit on morbidity, mortality from obesity.

But also all of the cardiovascular indicators that we reported out in that Phase 3 study, including a very significant drop in blood pressure that should have a benefit -- drop in LDL, an increase in HDL, a drop in triglycerides, all of that should contribute to cardiovascular outcomes. So we remain excited and confident about our own study going forward.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Anne?

A - Anne White {BIO 20764375 <GO>}

Yes, Louise. Thanks for the question on Alzheimer's. So the fact is bottom lines, we remain convinced about the mid and long-term opportunity for donanemab and the Alzheimer's portfolio. Our focus right now is obviously on the rapid availability of donanemab for the appropriate patients through the accelerated approval pathway and then reconsideration with Phase 3 data and we remain optimistic that with -- particularly with traditional FDA approval, FDA or sorry, CMS would not continue to limit coverage for on-label treatments. Now, obviously you mentioned competitor readouts. So as we've noted on prior calls, there is a chance that we'll see mixed results in some of these readouts due to the differences in the medicines and their trial designs. And as you know well, we have some unique design features in TB2 and a medicine that demonstrates rapid and deep plaque clearance. So we won't be discouraged if others missed their primary endpoints and so we'll be following that closely, obviously. But in the near term, of course, we have to acknowledge that patient access will be very limited under the current CMS and CD with

accelerated approval, but what that does do, the accelerated approval is really enable us to engage quickly with CMS following the -- that Phase 3 data and hopefully drive reconsideration at that point. And it also allows us to accelerate the traditional approval through a supplemental BLA.

So we'll do in the near term, following a potential approval and accelerated pathway is use that time to build out the diagnostic ecosystem to help physicians with the referral process and infusion systems and so there is quite a bit to do, I think to get ready for that Phase 3 data.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anne. Louise, thanks for your questions. Next caller, please.

Operator

The next caller is Terence Flynn from Morgan Stanley. Please go ahead.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks so much for taking the questions. Two from me. I guess Mike, you talked about aiming for long-term success with Mounjaro from a reimbursement perspective. So can you just maybe define that for us, put a finer point on it? Should we assume that means, you're aiming for a net price above Trulicity ultimately over time. And then as we think about your ability to supply the market here obviously launch, you said at the high end of your expectations, Anat, I think you touched on this a little bit during your comments in terms of confidence in US supply. But how are you thinking about the broader supply dynamics globally and then remind us your flexibility to increase supply if needed over time? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Terence. We'll go to Mike for both questions on Mounjaro both access and price and then just global supply outlook.

A - Mike Mason {BIO 18347681 <GO>}

Okay, thanks, Terence those questions. Long term, I think our goals there is obviously to optimize our net price but also secure broad access like we have for Trulicity. So those are our two goals. Obviously, we don't give specifics on our net price negotiations publicly, but we're pleased with the progress, we're staying disciplined, trying to accelerate access before any new product launch. You got to be careful that you're not too aggressive, you get access too early but you pay too much for it. So we're staying disciplined. We've got a great product with a great profile. Payers are seeing that, but it's a process and we're going through that process right now.

From a supply perspective, on Mounjaro, as Anat said, we are planning for success. And so we have a lot of different launch scenarios and we have launch scenarios that consider this level of uptake. As Anat shared, we don't anticipate any supply constraints for the US launch of Mounjaro. We -- our manufacturing team has been working around the clock for

years to build manufacturing capacity throughout the supply chain. We have a number of sites, we make this and they're optimizing our initial capacity on a daily basis. Also, we have made investments to expand our capacity over the next several years.

We have a new parental plant at Research Triangle Park in North Carolina that's coming on line in 2023 and another one behind that in Concord, North Carolina. Also, we're building two manufacturing facilities to make (inaudible) for Mounjaro and those will go on -- come on at a later time. So obviously, we're planning for success and our manufacturing team is working around the clock to get as much supply as possible.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Mike, Terence, thanks for your questions. Next caller, please.

Operator

Next caller is Tim Anderson with Wolfe Research. Please go ahead.

Q - Tim Anderson {BIO 3271630 <GO>}

All right, thank you. On the Outcomes trial for obesity, presumably, that's a cardiovascular Outcomes trial we have made with a primary endpoint, and if so, what level of benefit are -- will be powered to show Novo's -- is designed [ph] to show 17%. Then on the head to head versus those product in obesity. Anything you can see on trial design, specifically primary endpoint and perhaps most importantly, the timing of having results? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Tim. We'll go to Dan for the first question on SURMOUNT MMO and then, Mike, for the second question on the head to head trial with Novo (inaudible)

A - Dan Skovronsky {BIO 15349505 <GO>}

Thanks for that question, Tim. You're raising an interesting point. I think implicit in your question is -- is the observation that there's a lot of health benefits that come from losing weight. Obesity is a risk factor for a number of things, not just the things that are traditionally measured in cardiovascular outcome studies or May [ph] studies, so probably also noting, we've called this a morbidity-mortality outcomes MMO in obesity rather than CVOT. But beyond that, I think we've intentionally not got into details on the primary endpoint or the powering assumption. So that is yet to be disclosed.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Dan, Mike?

A - Mike Mason {BIO 18347681 <GO>}

Yeah, on the head to head versus sema 2.4 milligram, there has been no head to head trials comparing tirzepatide to sema 2.4, so we believed, it was a good opportunity to do that to demonstrate tirzepatide's significant weight loss benefits in totality, the benefits it has for patients. Head to head studies are the gold standards. Every time we talk to

healthcare professionals, they really value and get a lot out of head to head studies. It just really informs their treatment. So we think, it's the right thing to do and we're pleased to do that. It's going to be a head to head study, where we're comparing tirzepatide versus sema 2.4 in people that have obesity and overweight with the weight related co-morbidity [ph]. Other than that, we will provide more on the design and the timeline at a latter -- later date as we get closer to posting that on clinicaltrials.gov.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Tim, thanks for your questions. Next caller, please.

Operator

The next caller is Steve Scala from Cowen, please go ahead.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. A couple of questions, first, Lilly mentioned in the prepared remarks, a limited availability of competitor GLP-1s in select geographies. Can you be more specific on which geographies and the magnitude of the issue? And then a question for Dan. You must have been on the receiving end of many calls from DSMBs with interim updates on trials, for example, the trial of Trulicity in cardiovascular outcomes rewind.

The question is what is the depth of the information exchange between DSMBs and sponsors at that time? For instance, if the studies continuing passed an interim, look is the conversation only three words, study is continuing? Or is it more extensive or does it depend, and if it depends, what does it depend on? It would seem to me at least counterproductive for a DSMB not to provide some guidance just from the vantage point of further development of the molecule. So that's my question. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Steve. We're going to go to Ilya for the question on the supply and demand that we're seeing for Trulicity outside the US and then we'll go to Dan for for the second question. Ilya?

A - Ilya Yuffa {BIO 21952737 <GO>}

Yeah, Steve. Thanks for the question. First, what we've seen is an accelerated demand for Trulicity in many of our international markets and it's probably three sources that one, great commercial success. We've been really successful in our diabetes portfolio in driving the growth and utilization. Trulicity at the same time, we've seen accelerated market growth and we have seen in some select markets the amplified demand for Trulicity because semaglutide is not available in full extent in a number of markets. In terms of where, we've seen volatility in where that is occurring and so we are evaluating, the local situation is quite dynamic and we're ramping up as much as we can to meet this amplified demand, at the same time, in some of these markets, we're going to have to look at managing some of the growth and making sure we limit any kind of patient impact.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks. Ilya. Dan?

A - Dan Skovronsky {BIO 15349505 <GO>}

Yeah. Thank, Steve. I understand where your question is going and we probably don't weigh in specifically on what others might do or see. But I'll tell you how we run DSMBs and how we think about them generally across the industry. There is a couple of principles apply here. First of course is independence. This is not a -- something run by the sponsor and I think that's an important consideration for patient safety. We don't see the data. They see, and we're not privy to the discussions, as a rule.

The second is that we do set for DSMBs rules in advance, by which they should make decisions. Those could be very simple rules in some cases, like hit -- to hit statistical significance with a certain alpha on the primary endpoint or they could be more complex rules looking for consistency across secondaries or sub populations or higher bar of efficacy on the primary, so that you're sure that you have a compelling effect that varies from study to study and sponsor to sponsor I'm sure. The third thing is, that their recommendations that DSMBs give [ph] back to sponsors are often pre-specified. So we'll tell the DSMB, if it meets these criteria, this is what you tell us. And if it doesn't. This is what you tell us. And they usually are matter of fact, without color that could compromise the integrity or cause unintentional unblinding of an ongoing study. So I hope that's helpful in understanding how DSMBs work.

I think, at many companies, if there is surprising recommendation for DSMB, such as to stop a study, there will often be a process where the sponsor, one or two representatives of sponsor are unblinded, so they can confirm the DSMB conclusion before taking action, but that wouldn't be typical for a simple study continues kind of decision.

A - Kevin Hern {BIO 20557573 <GO>}

(multiple speakers) Thanks, Dan. Steve thanks for your questions. Next caller, please.

Operator

Next caller is Umer Raffat from Evercore. Please go ahead.

A - Dave Ricks {BIO 16504838 <GO>}

Hello Umer?

Operator

Looks like his line dropped. We'll move to Andrew Baum from Citigroup. Please go ahead.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. Couple of questions. First on Mounjaro. You uniquely have labeling requiring technical conception during titration, which Gogi [ph] doesn't have. The recent Supreme Court overturning (inaudible) with increased emphasis on the confidence in terms of risk of practice and given the consequences. How are you thinking about this? Whether it's

potentially an Achilles' heel for the product, whether through additional pharmacology studies that could be overturned and as -- did you see indication roll through, it does seem from the FDA review that there's a real pharmacologic concern rather than positive [ph] data here.

And then second, on the positive side, in relation to the pirtobrutinib filing, assuming you get approval in mantle cell, I'm assuming that you would therefore get inclusion in the MCM MCCA [ph] guideline for Bruins CLL, so could you talk to how you think the expedited approval through mantle cell may accelerate your penetration of the CLL market, whilst you're waiting for the Phase 3 trial programs to mature, many thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Andrew. We'll go to Mike for the first question on Mounjaro labeling in the social climate and then we'll go to Jake for the question on pirtobrutinib.

A - Mike Mason {BIO 18347681 <GO>}

Thanks, Andrew. I appreciate the question. Let me just even set everyone, our label on Mounjaro advices women using contraceptive -- oral contraception to switch to or add to a non-oral contraceptive methods for four weeks during initiation of the product and then during the dose titration for each dose. Given the -- so healthcare professionals are aware of this, given the profound benefits of Mounjaro, this hasn't impacted at all HCP and consumer interest in Mounjaro. If you look at the data in the marketplace, we have data with IQVIA through July 22, which is just five weeks of full promotion and we've -- and Mounjaro has already reached 20% new brand share of market, so we haven't seen this as a -- as an issue at all. As for the future works for and evaluating the issue, we have nothing new to report to investors at this time. But this has not been an issue that has impacted Mounjaro's uptake at all.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Mike, Jake?

A - Jacob Van Naarden {BIO 18103115 <GO>}

Yeah, thanks for the question. So just as a matter of policy, we submit company sponsored guideline requests on -- consistent with labeling indication that we actually intend to receive or expect to receive. So we'll do that in this setting as well, in the context of BTK pretreated relapsed proprietary mantle cell lymphoma. What that -- from there the NCCN and other guideline process is completely independent and has no involvement from us whatsoever. To the extent that they choose to do something beyond our labeled indication is really completely out of our hands and hard for me to speculate on. And of course, we'll be promoting the product only on the labeled indication that we received.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Jake, Andrew, thanks for your questions. Next caller, please.

Operator

The next caller is David Risinger from SVB Securities, please go ahead.

Q - David Risinger {BIO 1504228 <GO>}

Yes, thank you very much. So my questions relate to Mounjaro, please. First, could you clarify the shared gain percentages. So I believe the comment was that Lilly's combined Trulicity and Mounjaro share gained by 12 percentage points. So wanted to just understand what was the starting point and where is the figure today? And then there was also a comment about new to treatment starts, excuse me, gaining by 10%. So if you could provide the X to Y on that and then based upon your current view of the very strong US uptake of the product, to what degree is Lilly planning to gate its ex-US Mounjaro launches due to the manufacturing supply constraints that that you're currently up against? Thanks very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, David. We'll go to Mike for the questions around share gain. And then Ilya for the questions around OUS launch.

A - Mike Mason {BIO 18347681 <GO>}

Okay. David, thanks. I'll give you more context of the opportunities that we had earlier on in the call. So what we're looking at is IQVIA data at the beginning of that by our analysis is June 3. We had our launch meeting, the week after ADA. So the week of June 14. So we have been promoting kind of full on since then. And so when you compare to where we're at today, this is, we have IQVIA data through July 22. So five weeks of promotion, so we're comparing the -- our MBRX volume, our new to brand volume and share at July 22 versus June 13 in the injectable incretin market. And so what we've seen since then is that Mounjaro's MBRX share has reached 20.5. We saw Trulicity's MBRX has declined by only 8.4 -- the share points and so that produces a net gain in the Lilly injectable incretin MBRX share of 12.2%. And then with NTS, same time period, same market. We have a 10% overall Lilly injectable incretin MBRX share gain.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you, Mike. Ilya?

A - Ilya Yuffa {BIO 21952737 <GO>}

Yeah. David, thanks for the question on the launch of Mounjaro outside of the US and our thoughts around that. One of the key aspects of how we take a look at launching outside the US is typical for most product launches across pretty much all therapeutic areas to have some lag to US launches, either through because of regulatory approval and process but also pricing and reimbursement. And it can take up to a year to get reimbursement in a number of markets. So the volumes in that first year of launch are somewhat limited. We are encouraged by what we're seeing in the US launch of Mounjaro and looking forward to launching Mounjaro outside of the US and leveraging our commercial expertise and strength in Diabetes across our markets outside the US.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Ilya. David, thanks for your calls.

A - Dave Ricks {BIO 16504838 <GO>}

Maybe just, David, just to clarify there, because the way you framed your question, you said we're up against supply constraints. In the case of Mounjaro, as we said today in the prepared text. We don't anticipate supply constraints in the US, of course, before introducing a product in a new market, we want to make sure we could fully initiate new patients and supply and based on our competitors' actions, it's hard to predict a year from now, what will need in a given market. So it's not that we don't have supply. It's more the demand picture is unstable. We want to -- we're just cautioning that we want to know that before we initiated launch sequence. But we've launched in the US and we're committed to that supply. It's not that we have an issue. Just to be clear.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave.

Q - David Risinger {BIO 1504228 <GO>}

Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Next caller, please.

Operator

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

Q - Chris Shibutani {BIO 3202082 <GO>}

Thank you very much, two questions. The first on Mounjaro -- thank you for that information about the relative trend as far as where the source of patients were. Narrowing in on the question of what portion were actually switches from Trulicity that was helpful back of the envelope, it sounded like about 10%, is that about what you expected and where do you think that this will go, I am asking, and obviously, since we're relatively early stages of this launch.

Second question would be about Verzenio, actually to bring up something that seems a little bit less focused upon but performance has been strong and logically, it would seem to be in the adjuvant setting, but could you speak to what you believe is driving this? And what the outlook is for those trends that have thus far been delivering the strong performance there? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Chris. We'll go to Mike for the question on Mounjaro and then Jake for the question on Verzenio.

A - Mike Mason {BIO 18347681 <GO>}

Yeah. It's a good question. I think, we're getting what we expected. We thought we would see more new patients into the class. That's what we talked about with the healthcare professionals and that's what we're getting. So we're not surprised by that, pretty typical of what we'd expect with the new GLP launch.

What you would expect when you have a new product like Mounjaro especially with endocrinologist that they don't always see naive patients. They have a good bolus of patients who are already on GLP. And so when they -- we talked to them about Mounjaro, they are excited about the opportunity to actually switch some of their patients who are not performing or not at goal at the current GLP. And so I think early on, you will see like a higher percent coming from switches versus naive and so today, we have 72% that is naive. If you look at Trulicity, that's in like 88%. So what I would expect is that that percentage coming from navi will grow over time, but I think, this is what we would expect that launch and we're very pleased by both Trulicity and Mounjaro's performance since Mounjaro is launched.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike, Jake?

A - Jacob Van Naarden {BIO 18103115 <GO>}

Yeah, thanks for the question on Verzenio. We too are pleased with how this has gone so far this year, I think, to your question on why and where it goes from here, on the why, I think it largely comes down to the clinical data from the monarchy study itself. I think the data are demonstrable and when physicians and patients see them, they quickly want to integrate the drug into their practice.

Now in addition to that, and this is something we hope to see happen. We think, we're seeing some share gains in the metastatic setting as well, particularly among physicians who historically used other CDK46 inhibitors are gaining experience with Verzenio by utilizing it in the adjuvant setting and then starting to use it in the metastatic setting where perhaps they hadn't been before. So that was part of what we hope to might happen. I think we're seeing that happen a little bit so far this year. That having been said, in terms of where we go from here, I'll just say two things, one, we continue to interact with physicians who are still not yet aware of the monarchy data. And so that's, of course, good and bad. It's bad because there are patients who are appropriate for the medicine that should be on it. It's -- but it is opportunity to continue growing in the labeled indication that we have currently. And on that note, as we've talked about in the past, we're hopeful that we have the opportunity to expand the indication to the enrolled trial population for monarchy, and we're awaiting that analysis of overall survival, as we talked about in the past. So yeah, we're pleased with how it's going. We see plenty of opportunity ahead to continue the momentum.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Jake. Chris thanks for your questions. Next caller, please.

Operator

Next caller is Carter Gould from Barclays. Please go ahead.

Q - Carter Gould {BIO 21330584 <GO>}

Great. Good morning, thanks for taking the question, I guess, first off, can you talk about how pronounced the cash pay component was of the early Mounjaro numbers and how you expect maybe that to evolve. And then separately, maybe coming back to the drug pricing question but from a different angle, it would appear that Lilly could be one of the main beneficiaries from lower out-of-pocket costs on that side, and you think about sort of improvement in compliance. So can you maybe help frame that impact or maybe think about how compliance today differs in the US versus maybe other markets where those out-of-pocket costs are not akin -- don't exist. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Carter. We will go to Mike for the first question on Mounjaro and then Dave for the follow-up on drug pricing reform and the impact.

A - Mike Mason {BIO 18347681 <GO>}

Thanks, Carter. Thanks for the question. On the cash pay side, we expect the percent of cash pay to follow our percent access in the marketplace, what we've seen so far, again reiterate what I said earlier that we have both Part D and commercial access for Humana Express Scripts on the National Preferred Formulary, and Cigna, if you add that up, that's little over 20% of the national lives. And so I think that's probably the best -- best estimation of what you're going to see with the cash pay.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Dave?

A - Dave Ricks {BIO 16504838 <GO>}

Yeah, Carter. I think you're pointing out something, as I mentioned, we would be supportive as a freestanding measure to the Part D reforms that are in this reconciliation package for a bunch of reasons, one, it does, I think more fairly distribute the burden of the industry pay for into Part D. Today, the way the donut hole math works, if you go back a couple of years, we had a lot of earnings calls, we had to describe that. There is this really disproportionate contribution from the industry inside the donut hole, so commonly used medications like in diabetes and cardiovascular have a pretty big hit on that. That gets smoothed out. So now that -- drugs that hit the catastrophic pay more, and it's more of a balanced contribution independent of drug-type. That's a good thing for companies like Lilly that have more commonly used drugs.

The other thing though you're pointing out. And I think this really would affect the product like Verzenio for us, primarily is patients who get thrown into the catastrophic have this uncap 5% contribution today and we know that not only do patients discontinue and you mentioned about compliance rates, which are better in oral oncology in Europe, in the US for instance. But I think also, you will see more initiation because physicians and their family screen themselves out of even qualifying for an appropriate medication for

themselves because of financial burden and maybe go to chemotherapy instead of a more targeted therapy.

So that presents another way in which we can both improve healthcare in America but also prospects for medicines that Lilly makes. So those are good things. As I said, on balance, we still don't like going [ph] through the negotiation side, but those are positive elements.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Dave. Carter, thanks for your questions. Next caller, please.

Operator

The next caller is Kerry Holford from Berenberg. Please go ahead.

Q - Kerry Holford {BIO 21698599 <GO>}

Thank you. Please, firstly on price. You've clearly cited a low realized prices for drugs this quarter and taking in the US, and I'm wondering, if you can speak specifically to how that's evolving in the GLP-1 market? Any particular step up on Trulicity rebates since the Mounjaro launch. What are your expectations here going forwards? It is a trend, is higher rebates, negative channel mix noted by your competitor in their results call yesterday, so interested to getting your perspective here. And then a quick question for Anat, when do you anticipate having greater clarity on the possible repeal on the 2017 Tax Act? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Great, thanks, Kerry. We'll go to Mike for the question on incretin market price trends and then Anat for the question on tax reform. Mike?

A - Mike Mason {BIO 18347681 <GO>}

Yeah. It is good question. I think, naturally payers will ask for additional rebates when a new product joins in formulary. So as part of our discussion of the discipline on why you don't want to accelerate those discussions too rapidly and that's a factor into it. So I think, net-net, I don't expect any step changes in GLP pricing as a result of Mounjaro launching but as part of the natural pressure intention and contract negotiations.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Anat?

A - Anat Ashkenazi {BIO 19888043 <GO>}

So on taxes. What we're seeing is we're seeing broad bipartisan support for repealing that change of capitalizing R&D expenses. As was evident in the recent Senate letter, this could come, we believe it will come through by the end of this year, most likely if I had to guess, I would say towards the end of the year potentially as part of (technical difficulty)

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anat. Kerry, thanks for your questions. Next caller, please.

Operator

The next caller is Mohit Bansal from Wells Fargo. Please go ahead.

Q - Mohit Bansal {BIO 18070890 <GO>}

Great, thank you very much for taking my question. Maybe one question on the Select early study, the pre-diabetic study. So maybe one, for you, Dan. What you really need to show, how long the trial and what you need to show in terms of delta versus control to be -- to prove that it is beneficial in pre-diabetic patient and wouldn't oral GLP be a better drug for those patients. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mohit. So Dan, the question on SURPASS Early, the pre-diabetes study and then whether oral GLP would be better, Dan?

A - Dan Skovronsky {BIO 15349505 <GO>}

Yeah, that's an early diabetes study. But I think you're -- I don't believe we've disclosed the design of the endpoints yet, but I think with respect to diabetes prevention that's certainly very interesting area, and there are currently FDA guidance on what's required to show diabetes to prevent -- prevention of diabetes, to get that kind of claim. It's a very high bar. And I suspect the field will come to an understanding about which drugs can actually decrease the risk of getting diabetes, you prevent diabetes before any drug is able to get that indication.

I think this class of American -- medication particularly tirzepatide has great promise in that area, we highlighted that data from SURMOUNT-1 that showed the vast majority, more than 95% people were pre-diabetic in the beginning of study had normal glucose levels at the end of study, that's really promising, longer-term data, including drug washout data required to get to that kind of claim.

A - Mike Mason {BIO 18347681 <GO>}

Yeah, maybe if I can add, have you done? Yeah, I can add a few comments on that. This study is for people with diabetes -- have been diagnosed with diabetes and we want to test what the impact could be on their progression of diabetes, if you put out product like tirzepatide on very early in the course of treatment. And so this whole study putting -- starting patients who are naive or very early in their treatment versus standard of care, we think weight loss with the benefits of a GLP and GIP and the improvement in beta cell function and insulin sensitivity could have a profound impact of disrupting type 2 diabetes, and so that's what we're testing in a study. It's one that we're very excited about and we've already started to see weekly injectables being used earlier than just the injection space as more people understand that a weekly injection through an autoinjector is a good experience and actually some consumers prefer oral but some

actually consume -- prefer a weekly injection with an auto injector like Mounjaro and Trulicity has.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Mohit, thanks for your questions. Next caller, please.

Operator

The next caller is Evan Seigerman with BMO Capital Markets. Please go ahead.

Q - Evan Seigerman {BIO 18922817 <GO>}

Hi, all. Thank you so much for taking the question. So as part of the FDA acceptance of your accelerated approval filing for donanemab, have you got clarity from the agency if the iADRS scale is acceptable as an acceptable endpoint for full approval. And can you also talk about what you saw with the N3pG4 to move it into Phase 3. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Evan. Will go to Dan for those.

A - Dan Skovronsky {BIO 15349505 <GO>}

Yeah, thanks for the two Alzheimer's question, so first one is on the accelerated approval application for donanemab and whether that's an opportunity to gain more insight about acceptability of iADRS, which is our primary endpoint in the Phase 3 study. It may not be an opportunity actually because the accelerated approval is not contingent on an understanding of the cognitive or functional benefits of donanemab which we saw in the Phase 2 trial. Instead, the accelerated approval is just simply contingent on demonstration of lowering amyloid level. So I'm not sure, we'll get into deep discussion of that, although clearly, it's relevant in terms of the confirmatory study TRAILBLAZER-2. The second question that you raised was with respect to Rumtunatug, N3pG4 molecule. This is next-generation anti-plaque or plaque removing antibody designed to attack the same pyro-glutamate residue that donanemab goes after. We've seen robust ability of this molecule to clear plaques in patients. Remember that a liability or potential liability of donanemab is anti-drug antibodies and so, we've also noted that this molecule doesn't have that issue.

So given the potent robust clearance of plaques combined with lack of ADAs, we think this is amenable to alternative dosage forms that could be more convenient to patient. So we'll be looking at that.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Even, thanks for your questions. Next caller, please.

Operator

The next caller is Robyn Karnauskas with Truist Securities, please go ahead.

A - Dave Ricks {BIO 16504838 <GO>}

Robyn? Okay. Perhaps we could move to the next caller.

Operator

And the next caller is Colin Bristow with UBS. Please go ahead.

Q - Colin Bristow {BIO 17216671 <GO>}

Hey, good morning. Thanks for taking the questions. And Kevin, thanks for the great work. On business development, we have two deals announced today. Can you just give us your updated thoughts on the areas of interest, deal size. And then just what your -- what's the feedback you're getting from potential targets on their willingness to transact given the market backdrop? And then secondly, just on donanemab, what's your latest thinking or if you had any interactions with CMS with regards to how a single successful Phase 3 trial would be viewed in the context of reimbursements? Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. I would invite Anat to weigh in on the BD question and then Anne for the donanemab question.

A - Anat Ashkenazi {BIO 19888043 <GO>}

Thanks. So on the business development side and in terms of areas of interest in what we're seeing in the marketplace given some recent changes in valuation, our areas of interest remain really unchanged from what we've had the last several quarters, which is our core therapeutic areas. So looking at potential breakthrough innovations in those areas in different stages of preclinical and clinical development as well as in areas of new modalities, where we talked about extension that we have in those areas. We do look at and what you've seen us do in the last 12 to 18 months is more earlier stage opportunities, where we can bring things into our pipeline to supplement our existing portfolio and add value as well as innovation in our core areas.

Valuations, well it has changed in the last 6 months or so. It has not historically been the rate-limiting factor in terms of pursuing business develop opportunity. It's really finding those breakthrough opportunities where we make those investments. I mean, you asked about kind of target engagement and whether or not those views have changed it -- we were looking at whether you're looking at partnership or acquisition, everyone wants to get to value if the opportunity is there, then we tend to be able to get to a and good spot.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anat. Ann?

A - Anne White {BIO 20764375 <GO>}

Thanks for the question on donanemab. So it's our belief that the data package for donanemab which includes obviously both TRAILBLAZER-ALZ and ALZ 2 should be sufficient to meet with CMS as described as that high level of evidence in the NCD, so the

TRAILBLAZER-ALZ obviously was the first disease-modifying Alzheimer's trial did successfully meet its primary endpoint and if TRAILBLAZER-ALZ 2 also delivers that direct evidence of clinical best benefit as we expect it would, then we'll engage with CMS to discuss that path quickly and broadly expand access to the treatment. And we have been engaging with CMS throughout the process and we'll continue to do so moving forward, and they've shown an openness to continue to meet. Obviously they noted in the NCD the promise of donanemab and they've shown a great deal of interest in understanding the TRAILBLAZER-2 Phase 3 program. And so I think, we'll have more clarity on the timing of reconsidering, we're able to share that data with them in mid '23. They've stated publicly, they are committed to rapid reconsideration. But I think, we'll have to update on timing once they have that data in hand, middle of next year and we discuss next steps with them.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Anne. Colin thanks for your questions. We've exhausted the queue. Dave for the close.

A - Dave Ricks {BIO 16504838 <GO>}

Okay, great. Thanks for joining us today and I just want to apologize for the technical challenges on the call, we'll get that cleaned up. We do appreciate you participating today and your interest in our Company and please follow up with our IR team including Joe Fletcher, our new leader, if you have questions, we have question, we not addressed today on the call. Have a great day.

Operator

Thank you, ladies and gentlemen, that does conclude our conference for today. Thank you for your participation and for using AT&T Teleconference service. You may now disconnect.