Q3 2020 Earnings Call

Company Participants

- Anne E. White, Senior Vice President and President of Lilly Oncology
- Daniel M. Skovronsky, Senior Vice President and Chief Scientific Officer
- David A Ricks, Chairman and Chief Executive Officer
- Joshua L. Smiley, Senior Vice President and Chief Financial Officer
- Kevin Hern, Vice President of Investor Relations
- Mike Mason, President of Lilly Diabetes
- Patrik Jonsson, President of Lilly Bio-Medicines

Other Participants

- Chris Scott, Analyst
- David Risinger, Analyst
- Geoff Meacham, Analyst
- Gregg Gilbert, Analyst
- Louise Chen, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst
- Umer Raffat, Analyst
- Vamil Divan, Analyst

Presentation

Operator

Ladies and gentlemen, thank you for standing by and welcome to Lilly's Q3 2020 Earnings Call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session, 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, Mr. Kevin Hern. Please go ahead.

Kevin Hern {BIO 20557573 <GO>}

Good morning. Thank you for joining us for Eli Lilly and Company's Q3 2020 Earnings Call. I'm Kevin Hern, Vice President of Investor Relations. Joining me on today's call are: Dave Ricks, Lilly's Chairman and CEO; Josh Smiley, Chief Financial Officer; Dr. Dan Skovronsky, Chief Scientific Officer; Anne White, President of Lilly Oncology; Patrik

Jonsson, President of Lilly USA; Mike Mason, President of Lilly Diabetes; and Ilya Yuffa, President of Lilly Bio Medicines.

We're also joined by Sarah Smith and Mike Czapar of the Investor Relations team. During this conference call, we anticipate making projections and forward-looking statements based on our current expectations. Our actual results could differ materially due to a number of factors, including those noted on slide three. Additional information concerning factors that could cause actual results to differ materially is contained in Lilly's latest Form 10-K and subsequent Forms 10-Q and 8-K.

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, a reminder that our commentary will focus on non-GAAP financial measures, which exclude the financial contribution from during 2019 and represent earnings per share as though the full disposition via the exchange offer was complete on January 1st 2019.

Now I'll turn the call over to Dave for some opening comments.

David A Ricks {BIO 16504838 <GO>}

Thanks, Kevin. Q3 was another important quarter for Lilly and the pharmaceutical industries progress in developing new medicines to treat COVID-19. I'm very proud of Lilly's work and we'll go into detail of the promising advancements made this quarter. However, I'd like to start by summarizing our overall business performance.

Clearly, this quarter's financial results came in below sell side analyst projections. While we don't provide quarterly guidance, I'll make a few high-level comments on several factors that did impact our Q3 results, and then Josh will go into more detail later.

First, as we've seen as we've discussed in the past, the impact of price on revenue can be volatile in the US. As we make estimates for rebates and discounts, obligations during the coverage gap of Medicare Part D, patient assistance programs and other liabilities. During Q3, the magnitude of adjustments was meaningful, predominantly related to our assumptions regarding our obligations during the coverage gap in Medicare Part D for Trulicity. While the impact was notable in Q3, this source of volatility normalizes when analyzing our results over the first nine months, as well as for the full year.

In addition, while we are encouraged our new prescriptions are trending toward pre-COVID levels, the recovery varies by class. We view this impact as transient. We remain confident in the underlying business and continue to manage our operations to deliver success over the long term. From an operating expense standpoint, we made significant investments in R&D to develop COVID-19 treatments. While we spoken before about our efforts to develop COVID-19 treatments, we've not quantified that investment level. In Q3, we were fortunate to see positive clinical data from multiple trials and this activity had an impact of about $0.12 on Q3 earnings per share.

Finally, after taking a pause on active promotion in Q2 to respect the impact of COVID-19 had on medical practices, we increased our investments in customer-facing activity and direct-to-consumer marketing in Q3 in order to accelerate our growth. While this did create a step up compared to our investment level in SG&A in Q2 2020 and versus Q3 2019, we believe our progress in Q3 sets us up for a strong finish to the year and to provide meaningful momentum into 2021. We have a number of opportunities to drive this growth through these investments in our existing commercial portfolio. These include our unique CV indication for Trulicity and the recently launched higher doses.

Pulling through access wins for talks and launching the recently approved non radiographic axSpA indication, and driving increased uptake of Verzenio through our differentiated data package, just to highlight a few. Looking at the underlying trends in Q3, we delivered revenue growth of 5% or 4% excluding the impact of foreign exchange. Despite disruptions on new patient starts from the global pandemic, volume growth was solid, increasing by 9% versus Q3 2019.

Our key growth products continue to be the catalyst for our business performance, and made up over half of our revenue during the quarter. International performance in Europe and in China was particularly strong as constant currency revenue grew 9% and 10% respectively, driven by our newest products.

For the first nine months of the year, our revenue grew by 6% driven by 12% volume growth. This growth was delivered during a period of significant disruption; the ways we launched new medicines, executed clinical trials and manufactured our products, have all been meaningfully changed during the pandemic, with some adjustments likely to remain as our business continues to evolve. We are proud of our efforts to ensure patients have access to medicines by maintaining our manufacturing plants and continuous operation and by developing potential new treatments for COVID-19. Operating margin as a percent of revenue was 26.2% for the third quarter. This is a decline of 230 basis points versus Q3 2019 but was depressed by $125 million that we invested in COVID-19 therapies during the quarter, excluding these exceptional activities, operating margin was 28.4%. We have confidence in our outlook and expect to deliver financial results within our updated guidance range with all lines at or above our original 2020 guidance, and to achieve our operating margin expansion plans excluding our investments in COVID-19 treatments.

The fundamentals of our business are strong and we remain well positioned for a period of sustained growth and margin expansion.

Turning to the pipeline in Q3, we made meaningful progress advancing our late-stage pipeline and developing potential COVID-19 treatments including FDA approval of additional doses for Trulicity for the treatment of type 2 diabetes; an important data readout for Verzenio in early breast cancer, approval in Europe for Olumiant in adults with moderate to severe atopic dermatitis, positive Phase 3 results from the Act II trial baricitinib in combination with remdisivir in hospitalized COVID-19 patients. Positive results of our COVID-19 neutralizing antibody monotherapy and combination therapies, and we presented new data on a potential new indication for Jardiance in collaboration with Boehringer Ingelheim.

I am encouraged by our company's efforts to develop potential new therapies to treat COVID-19 and working at unprecedented speed. This work would not have been possible without the tireless efforts of many employees of Lilly and the collaborative efforts across the industry; regulators and government. We continue to utilize external innovation and collaboration to augment our internal capabilities. This quarter we signed a number of business development transactions including the global expansion of our Tyvyt collaboration with Innovent. At the same time, we utilized our strong cash flow to return nearly $700 million to shareholders via the dividend.

Moving to slides five and six, you will see the full list of key events since our last earnings call. I would like to welcome Ilya Yuffa to our executive team as he assumes leadership for our biomedicine business unit. A 25-year veteran with a tremendous breadth of experience across our organization from finance, business development and sales to Six Sigma, ethics and compliance and general management. Ilya has consistently delivered impressive results in successful larger roles that -- successively larger roles which have prepared him well to lead Lilly Bio Medicines. After serving as General Manager of Italy since 2018, Ilya has been leading Lilly's largest franchise US diabetes, where he played a critical role in the continued success of the market leading medicine Trulicity, as well as Jardiance in the 2 two fastest growing classes in diabetes. Ilya, it is great to have you on our leadership team.

I'd also like to thank Patrick for his energy, focus and execution that he brought to his time as President of Lilly Bio Medicines. Given Patrick's strong record of successfully managing Lilly businesses and complex markets around the world, he is the right enterprise leader to lead Lilly USA and our global customer focused functions during this exciting period of opportunity and growth, as we look to continue to deliver new medicines to patients.

Before I turn the call over to Josh to review our Q3 results and to provide an update on our financial guidance for 2020, I'm going to discuss briefly certain events at one of our manufacturing facilities located in Branchburg, New Jersey. Late last year, our Branchburg plant underwent a routine FDA general surveillance inspection. The Inspectors identified findings related to data handling and we received an official action indicated notice, as well as a follow-up inspection this year. We have not received a warning letter or other enforcement letter from the FDA at this time. Given that this plan is among several worldwide that produces bamlanivimab or Lilly SARS CoV555 one of our COVID-19 neutralizing antibodies, I want to share more information about our response to these inspections.

First, we are confident the issues raised during the inspections did not impact product quality or patient safety for bamlanivimab or for any other product manufactured at the Branchburg plant. Having said that, we and I take remediation of these data handling issues and our commitment to quality and safety very seriously. We engaged an external firm to conduct a comprehensive independent review of systems at the Branchburg site and we are working diligently to incorporate suggestions for improvement to our procedures. We have also had this firm perform independent reviews of our manufacturing of bamlanivimab at Frankfurt to examine our manufacturing batch records and quality documentation to corroborate our own batch release decisions as we submit

for supply of bamlanivimab from Branchburg for the Emergency Use Authorization we requested.

We are confident in the material at this facility, and frankly at all of our sites. Finally, for our neutralizing antibodies, we have a robust global supply chain in place with five active ingredient manufacturing sites worldwide, in addition to five additional drug product sites worldwide.

Branchburg is one of the active ingredient sites. Once we are approved to do so our resilient global network is well positioned to begin the supply as we help battle this global pandemic. Now let me turn it over to Josh.

Joshua L. Smiley {BIO 19888026 <GO>}

Thanks, Dave, and good morning everyone. Moving to slide seven and eight, you will see our non-GAAP financial performance in Q3 and during the first nine months of 2020. As Dave mentioned, revenue increased 5% this quarter compared to Q3 2019, as key growth products drove volume growth. Gross margin as a percent of revenue in Q3 was 79.1%, a decline of 50 basis points versus Q3 2019, driven primarily by the unfavorable effect of foreign exchange rates on international inventories sold and lower realized prices, partially offset by favorable manufacturing efficiencies and product mix.

Moving down the P&L, selling, general and administrative expenses increased 11% this quarter compared to Q3 2019, as we invested meaningfully in direct to consumer marketing to augment our virtual tactics. increasing promotion to physicians and consumers in connection with increases in healthcare utilization around the world.

As I'll discuss in our guidance in a few minutes, we see the absolute level of third quarter SG&A expenses as indicative of our fourth quarter expenditures as well, which keeps us on track for our full-year ranges and modest full year growth. Research and development expenses increased by 6% in the quarter, driven primarily by our efforts to develop COVID-19 neutralizing antibodies and baricitinib for hospitalized COVID-19 patients, partially offset by lower development expenses for late-stage assets.

In total, operating income decreased 4% compared to Q3 2019 as increased investments, including COVID-19 related R&D expenses exceeded revenue growth during the quarter. We expect the increased marketing activity and customer activation to drive additional revenue growth going forward. During the first nine months of 2020, operating income increased by 7% as revenue growth outpaced operating expense growth.

Operating income as a percent of revenue was 26.2% during the third quarter and 28.1% for the first nine months of 2020. As Dave mentioned earlier, our investments in COVID-19 therapies represent an investment outside of our normal business operations. So excluding R&D expenses of $180 million associated with these important programs, our operating margin during the first nine months of 2020 would have been 29.2% and consistent with our guidance, we expect continued improvement in Q4. We continue to allocate resources efficiently in an environment where COVID-19 is likely to have an impact for a sustained period of time. We've made the transition to a hybrid virtual and in-person

commercial model to support executing our strategy and we're committed to margin expansion in 2020 and beyond.

Other income and expense was income of $159 million this quarter compared to expense of $25 million in Q3 2019. This quarter's other income was primarily driven by investment gains across our portfolio of public and private biopharma company investments as part of our external innovation strategy. As we regularly highlight this line can be volatile as public and private equity valuations fluctuate. We received quite a bit of investor feedback on this item, so beginning in 2021, we will exclude the gains or losses due to equity investments from our non-GAAP measures.

We believe this will better align our non-GAAP results with our core business operations, allow for easier comparisons with our peer group and remove unpredictable volatility. This quarter, our tax rate was 15.5%, an increase of 380 basis points compared with the same quarter last year, driven by the mix of earnings in higher tax jurisdictions and lower net discrete tax benefit this quarter versus the same quarter last year. While we expect some quarterly variability, we remain comfortable with long-term expectations of roughly 14% to 15% tax rate under the current US corporate tax structure. At the bottom line, earnings per share increased 4%. During the first nine months of 2020 earnings per share increased 20%.

On slide nine and ten, we describe the effect of price, rate and volume on revenue. Worldwide revenue increased 5% during Q3, as volume growth of 9% was partially offset by price. Foreign exchange rates had a 1% positive impact on revenue growth. During the first nine months of 2020, revenue grew 6%, driven by volume growth of 12%. Price was at 6% drag on worldwide growth, or 4% if you exclude the impact of Alimta and Tyvyt in China.

US revenue grew 3% compared to the third quarter of 2019. Volume growth of 7% was led by Trulicity, Taltz and Verzenio, partially offset by increased competition for Forteo, and the impact on Tradjenta from the restructuring of the BI Alliance. In line with our expectations, price was a 4% drag on US revenue growth. Three percentage points were due to changes to estimates for rebates and discounts, most notably impacting Trulicity. One percentage point was due to the net impact of increased rebates across the portfolio to maintain our strong commercial access, partially offset by modest list price increases.

While typically we do not discuss detailed pricing dynamics for individual products, I will provide some additional commentary on the impact of price on Trulicity performance in Q3. In prior quarters, we assumed our Part D coverage gap liability would shift to later in the year due to short-term deferral of healthcare utilization caused by the impact of COVID-19 and the increased threshold for entry into the coverage gap.

However, informed by recent invoices from our Part D customers, we now anticipate similar pattern to prior years. So this resulted in updated estimates that led to a meaningful impact on Q3 results and a double-digit drag on Trulicity's growth rate. Our estimated coverage gap impact for the full year though is largely unchanged. Excluding

the impact of the onetime adjustments, Trulicity's price declined by high single digits in the third quarter versus Q3 2019 and low double-digits for the first nine months of 2020.

We expect a high single-digit price decline for Trulicity for the full year. Last year, we guided toward a mid single-digit price decline for Trulicity. We expected this to be driven by increasing rebate rates to maintain our excellent access, partially offset by modest list price increases and modest growth in more highly rebated segments. As 2020 has unfolded, the negative impact of price on Trulicity growth has been higher than we expected, primarily due to segment mix. On slide 10, we show the impact of segment mix and rate on Trulicity growth in 2019 and 2020. While rate was a pricing headwind, the net impact of modest list price increases and increased rebate rates has been mid single digits or lower which is consistent with our expectations.

Moving to segment mix, while the commercial segment continues to deliver robust growth, lower net price segments have grown significantly faster. This depressed Trulicity's reported growth by approximately seven percentage points in 2019 and six percentage points through the first nine months of 2020. This continued growth in 2020 exceeded our expectations and was primarily driven by Medicaid and to a lesser extent Medicare and other segments. Within Medicaid we experienced formulary changes in key states, faster than anticipated pull-through of access wins and expansion of total Medicaid lives this year. Trulicity currently has a 45% share of market across all segments and continues to be the market leading GLP-1.

We exited Q3 with a similar share of market in the commercial segment. However, consistent with volume growth, we gained 4.5 percentage points of share in Medicaid and other segments since Q1 2019 and finished the quarter at a 38% share of market. It's worth noting that utilization of GLP-1, as a class, is still immature and low market penetration suggest significant opportunity for additional growth across all segments. GLP-1s are used less in Medicaid and Medicare and we expect disproportionate volume growth in these segments to continue. Although these volume gains have a lower realized price in our commercial business, they do represent profitable business and enable Trulicity help more people living with diabetes.

So, as we projecting to 2021, we expect continued strong Trulicity access and performance across all segments, with modest unit price declines, and continued faster growth in lower price segments to result in high single digit total net price declines in 2021. However, I would note that this faster segment growth which contributes to the net price decline also shows up as higher overall prescription growth for GLP-1s as well.

Our outlook for total US pricing trends remains unchanged and we continue to expect mid-single digit price declines for the full year in 2020, as well as moving into 2021. This mid single digit price decline outlook includes, as we noted last quarter a modest impact in 2020 from the effect of increased US unemployment on segment mix, as well as approximately $100 million to $200 million of impact in 2021.

Okay, moving to Europe. Revenue grew 9% in constant currency, as volume grew by 10%, partially offset by price. Volume growth was positively impacted by Alimta in Germany due

to our patent appeal victory and a court-ordered injunction against generics that had entered the market as well as Trulicity, Taltz, Olumiant and Verzenio. In Japan, revenue grew 1% in constant currency. as 5% volume growth was partially offset by government mandated price decreases were effective March 2020.

Japan revenue benefited from a one-time sale of Cialis, as well as good volume growth from Verzenio and Trulicity, partially offset by increased competition for Forteo. In China, revenue grew 10% in constant currency driven by 51% volume growth, partially offset by pricing concessions from the inclusion of Tyvyt and Alimta in government sponsored programs. These programs help drive China's significant volume growth which substantially increased access for patients to these important cancer medicines.

We are excited about the momentum of our China oncology business and look forward to receiving regulatory action on Verzenio in the coming months. Outside of our oncology portfolio in China recently launched products, Trulicity, Taltz, Jardiance and Olumiant continue to have strong uptake. Revenue in the rest of the world increased 3% in constant currency, driven by increased volume from our key growth products, strong performance from Trulicity, Jardiance and Olumiant was partially offset by decreased Humalog, Forteo, Cialis and Humulin volume.

As shown on slide 11, our key growth products continue to drive impressive worldwide volume growth. These new medicines delivered nearly 13 percentage points of volume growth this quarter. The strong volume trend in our key products was partially offset by a mix of competition and lower utilization of post LOE product or Forteo, as well as reduced Tradjenta royalties from the restructuring of our alliance with Boehringer Ingelheim announced last year. We end the first nine months of 2020 pleased that our key growth products have contributed approximately 50% year to date volume growth.

Slide 12, highlights the contributions of our key growth products. In total, these brands generated nearly $3 billion in revenue this quarter, making up 52% of revenue. Though our key products are well positioned to drive strong performance over the long term, we continue to see an impact from reduced patient starts due to COVID-19. In Q3, we were encouraged to see new patient starts recover off the troughs experience in Q2 as the health system reopened around the world. While different classes have recorded different rates, most classes remain 10% to 20% below pre-COVID baseline.

On slide 13, we provide an update on capital allocation. During the first nine months of 2020, we invested nearly $6 billion to drive our future growth through a combination of business development, capital expenditures and after-tax investment in R&D, including the addition of lebrikizumab in a number of early stage agreements. In addition, we returned over $2.5 billion to shareholders via share repurchase and the dividend. We remain well capitalized and have the ability to access debt markets at attractive rates.

We expect to continue to enhance our long-term growth by acquiring first or best in class pipeline assets and we do not anticipate COVID impacts regarding travel or market uncertainty to affect our efforts.

Moving to Slide 14, you'll find our updated 2020 financial guidance, and this is based on our best estimates at this time. Key assumptions supporting the guidance include; healthcare activity will continue the positive trends seen in Q3, returning to historical levels as doctors utilize telehealth or in-person visits despite additional COVID-19 outbreaks. New patient prescriptions will continue to improve in the US. Pricing headwinds from increased utilization of patient affordability programs and changes in segment mix due to increased US unemployment will continue to be modest, and promotional spend will constitute a mix of in-person customer interactions direct-to-consumer advertising and investments in digital promotion.

While uncertainty remains regarding resurgent waves of COVID-19 and any resulting impact on the pace of economic recovery around the world, we do believe healthcare activity will continue to be a priority and that most patients will find ways to access healthcare. So based on these assumptions, we are maintaining our current full year revenue range. At the low end of the range, year-over-year sales growth in Q4 would be 8% to 9% percent, which while a step up from our third quarter growth rate is supported by current volume trends and our expectations of more limited price impacts in the US. Achieving the higher end of the range likely require some moderate sales from our COVID antibody, which we believe is possible, but of course, not certain at this point.

Moving down the income statement, our gross margin as a percent of revenue was unchanged on a GAAP and non-GAAP basis, we are narrowing our range for marketing, selling and administrative expenses to $6.0 billion to $6.1billion. We are narrowing our range for research and development expenses to $5.8 billion to $5.9 billion, with investment in COVID-19 treatments of approximately $400 million for the full year, likely to push us to the high end of our range. As Lilly continues to self-fund these programs, we believe these investments are critical to help combat the global pandemic. We are noting that our non-GAAP operating income, as a percent of revenue goal of 31%, excludes our substantial investments in COVID-19 treatments and any associated revenue with them.

Inclusive of these cost, we expect an operating margin of approximately 29%. While these investments put near-term pressure on our operating margin, they continue to be the right decision for our company and for society and post launch, we do expect these therapies to be accretive to our operating income. We're updating the range of other income and expense to $450 million to $600 million of income reflecting additional gains in our equity portfolio seen in the third quarter. As previously mentioned, this number is subject to volatility of the capital markets.

Turning to taxes, we are maintaining our GAAP and non-GAAP effective tax rate guidance at approximately 14%. Earnings per share are unchanged on a non-GAAP basis. Our GAAP EPS is expected to be in the range of $6.20 to $6.40. As I noted, with the revenue range EPS totals in Q4 will be highly dependent on COVID sales which is why we're maintaining a pretty broad $0.20 range as we head into the fourth quarter. We expect Q3 well positioned to continue delivering revenue growth and productivity, despite the impact of the COVID-19 pandemic.

We're proud of the investments we are making to help combat COVID-19 and are confident in the underlying strength of our business and our ability to overcome

challenges. Based on our current outlook for Q4, we believe we will exit the year with strong underlying momentum for 2021.

So, now, I'll turn the call over to Dan to provide an update on our ongoing efforts to develop treatments for COVID-19, a summary of key data disclosures in Q3 and an overall pipeline update.

Daniel M. Skovronsky {BIO 15349505 <GO>}

Thanks, Josh. Since our last call, we've made meaningful progress developing potential treatments for COVID-19, advancing key assets in our pipeline and presenting practice changing clinical trial data at major medical meetings. I'll begin with updates to our COVID-19 viral neutralizing antibody program, then I'll provide an update on the full pipeline, and I'll finish by highlighting key events since the last quarter.

Moving to slide 15, Lilly is testing single antibody therapy, as well as combinations of antibodies in several trials, across two different patient populations. First, in the treatment of recently diagnosed ambulatory patients and second in the prophylactic or preventative setting amongst nursing home residents and staff. The third more severely ill population of the hospitalized patients has been studied in the ACTIV-3 trial only. This clinical trial's being run by the NIH and is the only study evaluating the efficacy of bamlanivimab, also notice LY-CoV555 in hospitalized COVID-19 patients. Based on an updated data set from the trial reviewed yesterday by the independent Data and Safety Monitoring Board, no additional COVID-19 patients in this hospitalized setting will receive bamlanivimab.

The Board's recommendation was based on trial data suggesting that the addition of bamlanivimab to remdesivir and other treatments used in the hospitalized setting is unlikely to further help hospitalized COVID-19 patients recover from this advanced stage of their disease. In this updated data set, differences in safety outcomes between the bamlanivimab and placebo groups were not significant.

Importantly, all other studies of bamlanivimab remain ongoing including ACTIV-2, the NIH sponsored study in recently diagnosed mild to moderate COVID-19 patients; BLAZE-1, Lilly's ongoing Phase II trial and people recently diagnosed with COVID-19 in the ambulatory setting, which is studying bamlanivimab as monotherapy and in combination with etesevimab also known as LY-CoV016; and BLAZE-2, Lilly's Phase III study of bamlanivimab for the prevention of COVID-19 in residents and staff and long-term care facility.

While there was insufficient evidence from ACTIV-3 that bamlanivimab improved clinical outcomes when added to other treatments in hospitalized patients with COVID-19, we remain confident, based on data from Lilly's BLAZE-1 study, that bamlanivimab monotherapy may prevent progression of disease for those earlier in the course of COVID-19. While the results in hospitalized patients were disappointing, we don't expect this to affect our chances of success in prophylaxis or in early treatment. And we thank the patients, physicians and staff participating in all clinical trials of our neutralizing antibodies, including ACTIV-3.

Regarding the Lilly sponsored COVID-19 neutralizing antibody program, we made key advances in the third quarter, which include we initiated BLAZE-2, the Phase III trials studying post exposure to prophylaxis for residents and staff and nursing homes. We reported proof of concept data for bamlanivimab, monotherapy in BLAZE-1, demonstrating a reduction in hospitalizations in AR visits in the outpatient setting. We reported that the combination therapy of bamlanivimab and etesevimab met the primary and secondary endpoints at an interim analysis of BLAZE-1 significantly reducing viral load and symptoms, as well as meaningfully reducing hospitalizations and ER visits in the outpatient setting.

And we submitted a request for Emergency Use Authorization to the FDA for bamlanivimab monotherapy in higher risk patients who have been recently diagnosed with mild to moderate COVID-19. We were particularly encouraged to show that neutralizing antibodies can help people clear virus more quickly, improved symptoms and most importantly prevent serious medical outcomes, like hospitalizations and ER visits. Notably the full data of monotherapy and combination therapy showed a reduction of hospitalizations and ER visits of greater than 75% across all patients.

In addition to monotherapy and combination therapy had an even larger effect size in high-risk patients, defined by body mass index or age. We've now dosed approximately 1,000 trial participants with bamlanivimab alone or in combination with etesevimab, and we've shared safety and tolerability data for more than 400 patients in the monotherapy and combination therapy or arms of BLAZE-1 on our call earlier this month, where we noted that monotherapy and combination therapy were both generally well tolerated with no significant safety concerns.

No clinically meaningful differences in treatment-emergent adverse events were observed across the treatment groups and the majority of treatment-emergent adverse events were mild to moderate in severity. And there have been no drug-related serious adverse events reported thus far. We continue to recruit patients in BLAZE-1 while the FDA is still reviewing our request for EUA for monotherapy. We will soon be ready to request Emergency Use Authorization for combination therapy and we intend to submit that request to the FDA as early as November.

Another achievement this quarter, as part of our efforts to develop potential treatments for COVID-19, was the positive outcome of baricitinib in the NIH sponsored Act II trial of hospitalized COVID-19 patients. Baricitinib in combination with remdesivir significantly reduced time to recovery and improved clinical outcomes. The numerical decrease in mortality compared to remdesivir alone was also demonstrated. These results were most pronounced in patients receiving oxygen.

Based on these data, we submitted a request for Emergency Use Authorization for baricitinib to the FDA and global regulatory discussions are ongoing, with two submissions to the FDA this month for requests for Emergency Use Authorizations, and with our neutralizing antibody combination therapy providing the potential for third in November.

I'm particularly proud of the progress we've made over such a short period of time to rapidly develop potential new solutions to aid physicians and patients in the battle against this pandemic.

Moving to slide 16, you can see our select pipeline opportunities as of October 20th. Movement since our last earnings call includes; approval for Trulicity alternative dose, approval for baricitinib in moderate to severe atopic dermatitis, the previously mentioned initiation of the BLAZE-2 Phase III trial, the advancement of immunology programs into Phase II, the initiation of two Phase I programs, and the termination of a Phase I diabetes asset, and termination of our Ang 2 antibodies Phase II proof of concept study in COVID-19 due to futility.

We also saw our results from the Phase II trial of Mevidalen, our D1 positive allosteric modulator, in patients with Lewy body disease. While we were disappointed that the study did not meet its primary cognitive endpoint at week 12, Mevidalen did show encouraging motor and non-motor benefits, and we are evaluating the next steps for this program at this time. In addition, Pfizer and Lilly have been informed by the US FDA, but the agency intends to hold an Advisory Committee meeting, likely in the March 2021 timeframe, to discuss the tanezumab application. As a result of the FDA's review, will obviously extend beyond the current December 2020 PDUFA date. However, the FDA has not provided a new action date. The agency communicated that its review of the application is ongoing and it has not requested any new clinical studies to be completed at this time.

Pfizer and Lilly will continue to work with the FDA, as they complete this review of the application.

Moving to slide 17, we provide an update on our 2020 key events. The first nine months of 2020 have been incredibly productive, that's highlighted by a significant number of positive key milestones. With only a few exceptions, we've delivered on the key events that we outlined back in December 2019 and we've added several more events. Most notably, since the last earnings call, we've had regulatory approvals for important new indications in line extensions for Trulicity, Taltz and Olumiant. In collaboration with Boehringer Ingelheim, we also presented results from Emperor Reduced trial, in patients with heart failure with reduced ejection fraction or HFrEF. Jardiance demonstrated a 25% reduction in cardiovascular death or heart failure hospitalization.

In addition, Jardiance had a positive effect in key secondary endpoints including first hospitalization for heart failure and an exploratory renal composite endpoint. Emperor Reduced, included patients with and without diabetes, and these data are encouraging to expand the use of Jardiance in patients with HFrEF. They also add to the existing body of evidence showing the cardiovascular real benefits of HFrEF, as first demonstrated in the EMPA-REG outcome trial. We are on track to submit these data to regulators later this year and look forward to the Emperor preserved trial in HFpEF in 2021. We also presented important data for Verzenio in early breast cancer at the virtual ESMO meeting this quarter, confirming that Verzenio is the only CDK46 inhibitor to demonstrate benefit in this population and the first advancement for these patients in almost two decades. Verzenio showed a 25% reduction in risk of cancer recurrence at a two year landmark analysis. Verzenio also reduced the risk of distant metastasis by 28%, an essential objective for any

novel therapy in HR positive HER2-negative early breast cancer, as distant recurrence is currently an incurable event.

This is an important observation that bodes well for overall survival, since according to published literature improvements in distant relapse-free survival have been shown to be a leading indicator for improved overall survival. The monarchy study is ongoing, study participants will remain on trial and continue to be followed and additional results will be presented in the future. As we stated previously, we intend to submit for regulatory review by the end of the year. We anticipate a standard review timeline with the FDA.

While there have been many positive pipeline events already this year, we still have two important readouts to come yet this year and a number of updates that will occur during the first half of 2021. Before year-end, we'll present additional data from the Phase 1/2 BRUIN study for our LOXO 305, our BTK inhibitor.

We'll also have top line results from SURPASS 1 the first Phase III trial to readout from the tirzepatide of type 2 diabetes program. SURPASS 1 is a placebo-controlled monotherapy trial. We look forward to sharing these data in the coming months for this important program that we believe will raise the bar for treatment expectations for patients with type 2 diabetes.

We have a lot of momentum in R&D at Lilly, which will carry into 2021 where we have a number of additional data readouts, including the remainder of the registrational phase III tirzepatide type 2 diabetes trials. Phase III data from mirikizumab and ulcerative colitis, Phase III data from Lebrikizumab in atopic dermatitis, Phase 3 Jardiance Hrfpef data, Phase II data from two Alzheimer's trials, including an important readout from our plaque clearing antibody, donanemab, expected early in Q1 2021. We remain excited about the potential of this molecule to make a real difference for patients with Alzheimer's disease.

Finally, we look forward to multiple potential proof-of-concept studies from our early stage portfolios in immunology, neuroscience diabetes and oncology. We've risen to the challenge this year as we engaged in the fight against COVID-19, we showed our adaptability and commitment to developing medicines through innovative ways. I'm inspired by the indefatigable effort by our teams in their pursuit of new medicines for patients.

Dave, back to you for some closing remarks.

David A Ricks {BIO 16504838 <GO>}

Thanks, Dan. 2020 has been a difficult yet remarkable year. Despite challenges and the resulting choppiness of our quarterly results, we've delivered volume driven growth of 6% through the first three quarters of this year. Excluding investments in COVID-19 therapies, we've expanded our operating margin by 160 basis points, compared to the first 3 quarters of 2019.

We've made meaningful progress this year on our innovation-based strategy, launching three new medicines and a number of NILEX, delivering important data readouts for key pipeline molecules and developing and submitting EUAs for potential treatment for a virus unknown to the world at this time last year. And over the next few months, we have several highly anticipated pipeline readouts on deck.

We continue to look for opportunities to augment the future growth of our company through business development and then return excess capital to shareholders. While the COVID-19 pandemic will continue to challenge us, the growth products in our commercial portfolio, limited patent expiry in the next five years and margin expansion opportunities before us, as well as upcoming data readouts in the pipeline, I like our prospects and I thank my Lilly teammates for persevering and performing amidst a year of challenges to continue to deliver meaningful innovation for the patients we serve.

This concludes our prepared remarks and now I'll turn the call over to Kevin to moderate the Q&A.

Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. We'd like to take questions from as many callers as possible, so we ask that you limit your questions to two per caller. Willis, please provide the instructions for the Q&A session and then we're ready for the first caller.

Questions And Answers

Operator

Thank you. (Operator Instructions) And our first question is from Louise Chen from Cantor. Please go ahead.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my question here. So, my first question for you is, why did you lower or tighten your 2020 guidance and leave the antibody sales as upside, are you having a high degree of conviction behind this Emergency Use Authorization, or are you seeing some positive trends shape up for the fourth quarter? And then, my follow-up question is what are your thoughts on the upcoming FDA AdCom meeting to review bids (inaudible) do you think this will close the door on Alzheimer's drug development or herald a new beginning? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Louise. We'll go to Josh for the first question on guidance and then Dan to the question on the FDA Adcom.

A - Joshua L. Smiley {BIO 19888026 <GO>}

Yeah. Thanks, Louise. Yeah, I think as we look at sales guidance on the implied Q4 absolute numbers, we see the trends. Now, we're at the end of October. I think we feel

good about the lower end of the range for sure based on just commercial performance of our products around the world. We have submitted an EUA, Dan talked about the data behind that. So, I think it's reasonable to include a potential upside associated with some sales of that antibody to governments around the world in Q4. Of course, it is uncertain, that is why we have kept the range.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh, Dan?

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

Yeah, thanks Louise for the question on the AdCom. Of course, like everyone else, we'll be watching it with great interest. But I don't think I can handicap it one way or the other. The way I see it, the important observation here is around the evidence lowering plaques can lead to cognitive benefits in Alzheimer's disease. I think we've seen it across a couple of data presentations now and that's what gives us confidence in our own donanemab, our N3pG antibody that's currently in Phase II. Just as a reminder, this is a pretty large Phase II. We've designed it with special care, enrolling a very homogenous group of patients so that it could be powered to show us an efficacy signal, if present, and we look forward to seeing that data early next year.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

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

Q - Tim Anderson {BIO 3271630 <GO>}

Hi, I have a question on tirzepatide. Important event coming up. Your first readout of Phase III, can you characterize your level of confidence that the Phase III results will wow investors, kind of like the Phase II results did? It's notable that analysts already carry a $5 billion number for this, which is a high number, and I'm wondering if you can talk about both efficacy and tolerability and safety relative to Phase II in terms of what you expect. I know that's asking you to predict how these readouts go, but it's what we have to do as investors. So it'd be great to get your best guess on that. And related to that question, how much data can we realistically expect that you will provide in a top line press release?

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Tim, we will go to Mike Mason for those questions.

A - Mike Mason {BIO 18347681 <GO>}

Yeah, thanks for the question. We appreciate it. We've never been more excited about our tirzepatide program in our Phase II type 2 diabetes studies, 43% of people on tirzepatide had reached a final A1c of 5.7%, which is normal A1c versus only 2% for the market leader Trulicity. 34% of people on tirzepatide lost more than 15% of their body weight versus 2% for Trulicity. And tirzepatide will be delivered in the same patient friendly device as

Trulicity. Tirzepatide has the opportunity to become a foundational treatment for someone living with type 2 diabetes that not only need A1c control, but can benefit from significant weight loss which brings additional metabolic health benefits. Further, we are very excited about what Tirzepatide could do in obesity and NASH. As we take a look at the results from SURPASS 1, later this year, we'll get the results. We'll issue a press release that will likely be top line results. We won't have full data be able to do a full analysis that will come later at medical meetings in 2021.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Thank you. And that will come from Umer Raffat from Evercore ISI. Please go ahead.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my question. I have one for Dan and one for Dave, if I may. Perhaps maybe starting with you, Dave. On the Alzheimer's A4 trial, you've previously expressed openness to possibly taking an interim analysis. I know you have two years plus of follow-up by now already, maybe three years of follow-up by next year, is that something you're still open to? I just wanted to hear your thoughts.

And then, Dan, there is a little bit of confusion on tirzepatide perhaps in part because both the clinic trials, as well as the Lilly slide, suggest the trial had a primary completion in October, but when I map out when the last patient entered, which was the first week of February and add in the 40 weeks, which is the primary endpoint, it doesn't look like the trials met the primary endpoint yet in all the patients and they will probably be in November, and then some time to analysis. So, can you confirm if I'm off track there? Thank you very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Umer. Dave?

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

Well, I think you directed the A4 question on me, but probably Dan will be able to answer that better.

A - Kevin Hern {BIO 20557573 <GO>}

Dan, why don't you take the A4 question?

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

Thanks, thanks for both of those questions. Of course, A4 is an ongoing trial in patients who are pre-symptomatic. They don't yet have the symptoms of Alzheimer's disease, but they have amyloid plaques as decked by imaging and we are testing if solanezumab -- can now a higher dose of solanezumab can have a benefit in those patients. We haven't

commented on whether or not there could be opportunities for an interim look here, and right now we're just focused on the final analysis of that trial.

With respect to the timing of the tirzepatide trial and the details on clinicaltrial.gov, I can just reconfirm what we said earlier on the call, which is that we expect to have that data and top line it in coming months. It's obviously a major event for us and you can assume that when we get that data, we're going to turn around quite quickly.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

The next question is from the line of Gregg Gilbert from Truist. Please go ahead.

Q - Gregg Gilbert {BIO 3565226 <GO>}

Thanks. I'm going to start with another one on Alzheimer's, Dan, I'm not sure to what degree you can comment on this, but I'm curious how interrelated your studies are and the agency's view of aducanumab, maybe asked another way, do you think the agency can act on their application without seeing your data which is coming pretty soon? It seems to me that what you're bringing to the table is pretty important in the field. And then secondly, I know it's a little earlier, I was hoping you could talk to your growing confidence in the IL-2 approach, since you sign that collaboration a few years ago, it looks like there is some additional data coming at AACR as well, thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Greg. We'll go to Dan for both those questions.

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

Yeah, thanks. Thanks, Greg. Two good interesting questions. I think on our Alzheimer's disease, your question is, how will the FDA think about sort of a class effect here from multiple plaque long antibody show the same result, or if they shown different results. I don't know, I mean I can't speculate on agency actions. But I can say that it wouldn't surprise me if regulators around the world did take sort of the totality of evidence approach in Alzheimer's disease, which could be across multiple molecules in different trials to give confidence about a particular mechanism in this case of course plaque lowering.

But Having said that though, each molecule will still have to pass a certain bar of evidence for benefit versus risk in the intended to use population. I do think though that if ADU is deemed to have a positive effect and our drug ultimately has a positive effect, the convergence of those two events could bode well for both drugs, but there's a lot that has to happen before we get there.

With respect to IL-2. Yes, as this molecule progresses in clinical trials, we are growing more confident in the hypothesis that underlies this effort. This is a low dose pegylated IL-2

that's meant to stimulate T regulatory cells without stimulating effect or T-cells. And we've not presented data from Phase 1 that showed we had exactly that effect. In a dose-dependent way we can boost Tregs and we hope that that will have a modulatory effect on autoimmune disease. Based on our confidence in the biomarker here and the mechanism of action we've committed to starting a number of Phase II trials here in parallel to understand how these changes in regulatory T cells translates -- could translate to clinical benefits for patients in diseases like lupus or IBD or dermatologic diseases.

And so, those trials are starting, and we look forward to getting data from them.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

The next question is from Chris Scott from JP Morgan. Please go ahead.

Q - Chris Scott {BIO 20390090 <GO>}

Great, thanks so much for the questions. Just my question on Trulicity. It seems like there's two issues kind of impacting the quarter. The first was the timing of the donut hole impact and the second was this channel mix issue, if I was hearing it correctly. So, I guess on channel mix, is that the net of the unfavorable price, I guess balanced against the higher volumes, a net neutral versus your original expectations, or is volume only partially offsetting this kind of mix issue that you're dealing with, I guess on that product specifically?

And then, my second question was on margin evolution going forward. Should we be thinking about the 31% operating margin, ex the COVID investments as your baseline to grow off of as we think about 2021 and beyond, or should we still think about some kind of lingering COVID investments that could impact margins as we move through next year? Thanks so much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Chris. We will go to Mike Mason for the question on Trulicity, then Josh for the question on margin evolution.

A - Mike Mason {BIO 18347681 <GO>}

Yeah, thanks for your question. Overall, we're very confident about the growth potential of the GLP-class and Trulicity. The GLP-class is performing strong with TRx growth of 23% for the quarter during the COVID pandemic. Trulicity continues to hold market share leadership in the face of semaglutide with a 45% share of market. Overall Trulicity grew volume 26% in the US, at a time when patient office visits for type 2 diabetes remains 20% lower than last year due to the COVID pandemic. When you take a look at segment mix, what we're seeing is that Trulicity performed well in commercial and Part D holding market share leadership and growing gross sales year-to-date at 29% in commercial and 44% in Part D.

Trulicity second mix was really driven by stronger than expected performance, both share and volume, and growing lower price segments like Medicaid. Even at the lower prices, Medicaid growth brings profitable business for Lilly and helps people living with diabetes. I'll highlight one decision that we made during the early stages of the COVID pandemic. We were concerned about people in commercial insurance losing their jobs, moving to Medicaid, and having the stop take Trulicity because we had lower access in Medicaid. We didn't think this dynamic would be best for people living with diabetes during the pandemic, thus we prioritized improving our access in Medicaid to help people living with diabetes. For example, we were upgraded on California Medicaid early in Q2 and we've seen Trulicity volume account for Medicaid nearly double this year, which is really great for everyone.

I remain very excited and confident in Trulicity.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Mike, Josh?

A - Joshua L. Smiley {BIO 19888026 <GO>}

Thanks, Chris. On margin, so yes, so we've tried to separate out of the COVID investments this year which we mentioned will -- the expense will be in the range of $400 million for the year. As you know, we've been focused on 31% operating margin as a goal for 2020 and given the guidance that we presented, not including anything from COVID, we're confident we'll achieve that 31%. I think that's the right baseline to think about going forward on an overall basis.

Now, we will have COVID investments that move into 2021 as we continue the trials that we've already put up and running. Again, that we are expecting, given the submission of the EUA and the data that we have, that there will be at some point sales associated with those investments. I think if we look at just isolating the expense and the sales, we'll have to come back on that. We haven't -- we don't have prices or volumes or anything around the world. So, I think the COVID piece, in 2021, we will have some expense. But realistically, I think the way to think about our business is 31% operating margin excluding the extraordinary COVID impact, and margin expansion then in 2021, and really through 2025 as we've talked about.

So, I think COVID should help us I think from an overall economic perspective in that period if the product or products are successful. But really, I think the focus on long-term margin expansion sort of cuts through anything that we see in the near term on COVID and we're committed to those margin expansion plans that we've talked about pre-pandemic.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

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

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. A couple of questions. First, Dan, in the past when you have referred to very low dropout rates in SURPASS 1, were you referring to analysis on an intent-to-treat basis? I fear Lilly is preparing us for solid data on an efficacy estimate basis but less compelling on an intent-to-treat basis. And then the second question is, it was said earlier in the call that Lilly has never been more excited about tirzepatide, I thought that was an interesting choice of words given the importance of the event and the lack of clarity on the status of the trial at this point. It implies that you're more excited than you were in Q2 or Q1 or any time in between.

So, can you tell us if any member of management has any knowledge whatsoever of the results of SURPASS 1? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Steve. We'll go to Dan for the question on dropout rates. And then Mike can talk about the question on tirzepatide.

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

Sure. Thanks, Steve. What we said with respect to people dropping out of our clinical trials was that we hadn't seen an effect from COVID-19. We were quite worried about that in the early days of the pandemic when the tirzepatide trials had become fully enrolled and were some of the most important and largest trials that we've ever conducted, whether this new pandemic would cause people to stop participating in clinical trials, and we did see a bump up in dropout rates.

I think though what you're really interested in is people discontinuation from therapy, which could be different than dropout rates, and we wouldn't know that until we get the data from the trial. With respect to the two different analysis that you comment on the efficacy estimate versus real intent-to-treat analysis, you're pointing out I think that in Phase II there was a pretty big difference between these two analysis with the efficacy estimate showing better results than the pure ITT because a number of patients at the highest dose, the 50 milligram dose had dropped out due to adverse events.

But like I said, we don't know what's happening in SURPASS-1 yet. But when those data come, it will be important to look at those two analysis, our hope and the way we've designed this trial with a slower dose titration is to avoid discontinuations due to adverse events, which would show that a smaller gap between the advocacy estimate and ITT that we saw in Phase II.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Mike?

A - Mike Mason {BIO 18347681 <GO>}

Yes, I can assure you that no one -- any one at Lilly have seen the results for SURPASS 1 yet. I think my confidence in tirzepatide -- something new that we've seen is obviously there's

been a lot of attention on the dose titration scheme that we used in our Phase II, in the dose titration study, as well as at Phase III. We've used a more gradual titration approach in our Phase III trials and as we've seen the read out of (inaudible), as well as some of the novels step programs we used, similar gradual titration. We saw that those schemes did work and that we're able to produce GI profiles that were acceptable. So, that's the new data that we've seen and we're very confident in tirzepatide.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

The next question is from Geoff Meacham from Bank of America Merrill Lynch, please go ahead.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey guys, thanks for the question. Just had a few. Josh on Trulicity, if I'm hearing you correctly for 2021, you guys have gone for mid single-to-high single digit price declines. But for the rest of the broader diabetes portfolio and really overall, is it still mid single as an assumption and if you have formulary wins for Trulicity and Medicare, Medicaid, but at a lower price, what's your capacity to raise price down the road, and then second question is, just real quick one to ask if you're seeing any sort of halo effect in the marketplace from metastatic breast share for monarchy currently or do you think that's going to happen looking to 2021. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Geoff. We'll go to Josh for the questions about the overall US pricing and then Anne for the question on Verzenio.

A - Joshua L. Smiley {BIO 19888026 <GO>}

Thanks, Geoff. Yeah on Trulicity, I think as we think about 2021, we are looking at two separate pieces. I think the first is just the underlying unit price where we feel things haven't changed. We really see underlying unit price holding segments constant as being in that low to mid single digit impact. I think what we've seen now over two years is we're underestimating how fast segments like Medicaid can grow and that's what Mike talked about. So, I think I think given the fact that we continue to see good growth in Medicaid, the share performance and utilization is still lower than what we see in Commercial and our strong performance in that segment, as well as we've talked in prior calls, we expect some Medicaid expansion. We're seeing a little bit of that now. We expect that to persist into '21. That moves us from that mid-single digit Trulicity price to high single digit. So, it really is the fact that we do continue to expect faster segment growth in areas like Medicaid.

I think all that being said, I think we will continue to look at pricing as we have in the past. We now -- we price for the system we have today which is modest price -- list price increases and giving back a little bit more than that in rebates, that's what we've seen over the last few years. I don't anticipate that approach changing unless we have something

that changes on the legislative side that can get us as a industry more toward our net price environment as opposed to high gross rebates and that. But for 2021, we're sort of planning those things, at least till the beginning of the year won't change.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Josh. Anne?

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

Yeah, thanks for the question, Geoff, on Verzenio. So, Verzenio have had notable positive momentum right now in the currently approved metastatic breast cancer setting and you can see that it's steadily gaining market share. We have monthly TRx approaching 14% now and NPRx approaching 23%. And then you saw some of the sales being posted particularly worldwide growth of 49% and we're now market leader in NPRx in Japan at over 50%. So, definitely momentum. And what we continue to do is really grow the number of physicians who tried Verzenio and they continue to adapt with really a positive experience and they incorporate it more broadly into their practice. This, I think is primarily capitalize on the positive overall survival data from Monarch 2 in combination with fulvestrant.

But we do believe that the positive results from Monarch E are really providing them another strong example that Verzenio is differentiated from other CDK4 6 inhibitors. And even prior to those results, there was a steadily growing body of evidence that Verzenio is differentiated with the higher CDK4 6 activity, differentiated continuous dosing, a monotherapy indication, and then obviously this OS data, not just in the overall population, but in the primary (inaudible) resistance. So, we do think we're seeing a shift in people's perception that this is a best-in-class opportunity, both in the metastatic setting, and then potentially in the future as we bring it forward for a new treatment option for patients in the early breast cancer setting.

So, look forward to more work there.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

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

Q - Seamus Fernandez {BIO 7525186 <GO>}

Thanks very much for the question. So, one question for Dave and then a question for Josh. So, Dave, can you talk about key post election policy priorities for the industry and what specifically Lilly hopes to achieve with the challenges to 340B. And then, the question for Josh is, if implemented as written, what would be the biggest impact on Lilly's corporate tax rate under the abiding tax plan and is there a concern that this would have a significant relative impact on US corporations like Lilly versus OUS corporations? Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Seamus. Dave?

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

Yeah, thanks, Seamus. Of course, the landscape of post-election is not defined, so we'll need to wait for that to land before we get into too many speculations about that future environment. But I think we can say that as an industry as we sit around the table, and certainly here at Lilly, there's two basic problems in the US drug market that need to be untangled. One is, the patient out of pocket cost problem, where we're really the only country on the planet that indexes patient out of pocket cost to list prices that that's still happens highly, in a highly prevalent way. And actually the rate of growth in high deductible plans, including those on exchanges in ACA, is growing. So this problem is getting bigger, not smaller.

Of course, we think the answer there is to have cost sharing at least be based on some discounted number, much closer to actual price, and perhaps all of the discounts being passed through. There's other solutions, regulatory ones. Other ideas we have capping deductibles, reducing the amount of copay can be for any given transaction through regulation or other avenue. States have done that and I think we do see good impact on affordability and persistence when that's done. So, that's the highest priority for the industry.

The second priority, and you touched on 340B, is just reducing the amount of distortions in the system which create artificial winners and losers and shift money around healthcare based on drug sales which is inappropriate way to fund things in our mind. We'd like to see that disentangled. And that kind of services, as it relates to dispensing or formulary management, are based on something to do with the value of those services versus something to do with the drugs that are being dispensed. 340B is one example of that where high priced drugs move through covered entities at huge margin increases and those monies go to other purposes, not related to the drugs, patients pay more and losing that equation and we certainly lose in that equation.

So, as it relates to 340B actions and other channel actions, we're interested in kind of decomplexifying that and making the system work a little bit better for not just patients, but for the sustainability of the pharmaceutical industry. So, anyway, we'll focus on those things as we have been and we'll have to see what the tactics look like based on our (inaudible) outcomes here just a week away.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Josh?

A - Joshua L. Smiley {BIO 19888026 <GO>}

Thanks, Seamus. I think first, the tax system that we have in the US now does help us compete on a global basis for innovation. I think that's the biggest positive that we've seen. It is a complex system, but having a rate, an underlying rate that's more competitive with our European competitors allows us to attract innovation, keep it in the US. And I

think you've seen that in some of the acquisitions we've done including companies like (inaudible) so we're more competitive when we're competing against OUS companies that have a low corporate tax rate in their countries. So, we like that. I think as we look though to potential changes, I think the first thing I would say is having been through the last round here, there is a huge difference between what a high-level plan is and how it gets implemented and the details in that implementation or what actually drives the big point movements. I don't know that we could have sitting in 2017 predicted that we have a 15% rate, for example, as our long-term rate here.

So, there's a lot of work to be done if there is any kind of future tax reform coming, obviously the underlying US rate, it looks like it will go up. But I think we have a couple of advantages, no matter what happens, we invest heavily in R&D among the most heavily of any of our big pharma peers. So, we would hope and work to ensure that innovation is rewarded in any tax system going forward. And we have a pretty balanced manufacturing network; we make -- about half of our plants are in the US, and half are outside US. So, I think we were probably poised to take to take advantage of any changes that happen in the tax structure going forward, but there is no doubt that having a competitive sort of base rate for the US relative to our OUS peers is something that I think is really important for our industry.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

The next caller is Terence Flynn with Goldman Sachs. Please go ahead.

Q - Terence Flynn {BIO 15030404 <GO>}

And the question, just regarding LOXO 305, can you share any perspective on the registration path for the drug in CLL and if a head-to-head trial versus Imbruvica is still on the table? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Terence. Dan, we'll go to you for that question.

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

Yeah, I think at this moment, it's premature to talk about registrational path. But I can say that we look forward to releasing more data later this year and I think as we release that data, that's an opportunity to update on our current thinking on the development plan.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Terence, thanks for your question. Next caller, please.

Operator

The next question comes from David Risinger from Morgan Stanley. Please go ahead.

Q - David Risinger {BIO 1504228 <GO>}

Yes, thanks very much. I just wanted to clarify. So, with respect to Trulicity, I believe you said that the volume growth was 26% in the quarter, obviously the reported US sales growth was 5%, which suggests a 21 percentage point difference. So, either way, if that's right, if you could just confirm it, if not, if you could just give us the correct figures, but then could you -- for the difference explain the components? So, obviously last year in the third quarter, the company admits Trulicity sales expectations due to higher-than-expected rebates. So, the company had a very easy comparison versus the third quarter of '19 for Trulicity, yet obviously the sales disappointed this quarter.

So, if you could explain that 20% plus percentage point difference in terms of how much was due to rebates versus mix shift, et cetera? And then, also help us understand why the mix shift was a surprise given the Medicaid wins that you articulated? And then, well, actually, I'll just leave it at that. So, if you could address those, that would be great. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. We'll go to Mike Mason for that.

A - Mike Mason {BIO 18347681 <GO>}

Thanks for the question. As we take a look at pricing performance for Trulicity in Q3, when we take a look at the net impact of increased rebates to maintain access and list price, that was a 2% modest headwind in Q3 of this year. Segment mix was 6% and then the remaining of that was due to one-time events due to coverage gap estimates for rebates and discounts. So, that's the break down performance for Trulicity. And in Q3, you may not have been on earlier, as we take a look at Medicaid performance, we're performing quite well in the higher price segments of commercial and Part D. We grew gross sales in commercial by 29% year to date and Part D by 44%. When we take a look at segment mix, it's really driven by higher than expected Medicaid. We really have kind of a triple whammy going there where, as you say, COVID is driving more people into Medicaid.

We are also seeing that Medicaid in general is growing for Trulicity because Trulicity share is lower. And then, we did make a conscious decision to win access in Medicaid because we felt that we're going to see people going from commercial to Medicaid and we had a lower access in Medicaid than we did in commercial. So, we thought it was right thing to do for patients in order to increase Medicaid so someone didn't have to go off Trulicity if they lost their job during the pandemic. So, that's the breakdown. We're very confident in Trulicity in both pricing and volume going forward.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Dave, thanks for your question. Next caller, please.

Operator

And next question will come from Vamil Divan from Mizuho. Please go ahead.

Q - Vamil Divan {BIO 15748296 <GO>}

Great, thanks for taking my questions. So, just two please. One on Tanezumab. I know you mentioned the AdCom, I believe that the change from (inaudible) the FDA was saying that they were not going to do an AdCom, I don't know if you have any insights you can share just on what may have changed to leave them to do the Advisory Committee meeting? And then, second on maybe just going back to the Alzheimer's discussion from before, obviously, a lot of focus on Tanezumab early next year. I know you also have N3pG in Phase 1 development. I'm just curious if you could maybe talk about sort of how that would have differed from the one you have in late Phase II now, to give us a sense of why you're trying to change their potential? Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Vamil. We'll go to Patrick for the question about Tanezumab and then Dan for the question on N3pG in Phase I.

A - Patrik Jonsson {BIO 21139959 <GO>}

Thank you very much for the question. We had just updated by the FDA that the PDUFA date is no longer valid and that they are most likely planning to have an advisory board in the month of March. And actually, we don't believe this is necessarily negative, taking into account that we have a lot of data on Tanezumab and we have the 39 clinical trials and more than 18,000 patients treated, so we actually think even donanemab could be beneficial.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Patrick. Dan?

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

Sure. Thanks for the question on donanemab and the follow on N3pG molecule which you noted is in Phase I. One of the things that we saw with donanemab was that we had a great PD effect, we can clear plaques quite deeply and quickly, but we also had anti-drug antibodies. The antibodies weren't at a level that they affected the PK of the drug because we're giving pretty high doses of the drug. Still it's not optimal to have ADA against your drug. So, we created a next-gen N3pG that we hypothesized would have the same plaque clearing PD effect but not have anti-drug antibodies. So, that's the next one that you see there in Phase I, if donanemab turns out to be a success. It could be useful to have a follow-on molecule that doesn't have ADA. I also point out that in addition to donanemab in that following N3pG molecule, the other Alzheimer's molecule, we're really quite excited about is Zagotenemab, which is our aggregated Tau specific antibody and that'll be reading out later next year.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Vamil, thanks for your questions and I will go back to Dave for the close.

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

Great. Thanks, Kevin. Well, we appreciate everyone's participation in today's earnings call and your ongoing interest in Eli Lilly and Company. Please follow up with the IR team if you have questions that were not addressed today and I hope everyone stays well during this difficult time. Take care and we'll be in touch.

Operator

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