Q3 2019 Earnings Call

Company Participants

- Anne E. White, Senior Vice President and President of Lilly Oncology
- Dan Skovronsky, President of Lilly Research Laboratories
- Dave Ricks, Chairman and Chief Executive Officer
- Enrique Conterno, Senior Vice President and President of Lilly Diabetes and Lilly USA
- Josh Smiley, Chief Financial Officer
- Kevin Hern, Vice President of Investor Relations
- Patrik Jonsson, Senior Vice President and President of Lilly Bio-Medicines
- Unidentified Speaker

Other Participants

- Andrew Baum, Analyst
- Chris Schott, Analyst
- Damien Conover, Analyst
- David Risinger, Analyst
- Geoff Meacham, Analyst
- Louise Chen, Analyst
- Navin Jacob, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst
- Umer Raffat, Analyst

Presentation

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Eli Lilly Q3 2019 Earnings Call. At this time all participant lines are in a listen-only mode. Later there will be an opportunity for your questions. Instructions will be given at that time. (Operator Instructions). As a reminder, this conference call is being recorded.

I'd now like to turn the conference over to the Vice President of Investor Relations, Kevin Hern. Please go ahead.

Kevin Hern {BIO 20557573 <GO>}

Thank you. Good morning, thanks for joining us for Eli Lilly and Company's Q3 2019 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, our Chief Financial Officer; Dr. Dan Skovronsky, President of Lilly Research Laboratories; Anne White, President of Lilly Oncology; Enrique Conterno, President of Lilly Diabetes and Lilly U.S.A; Patrik Jonsson, President of Lilly Bio Medicines; and Mike Mason, incoming President of Lilly Diabetes. We're also joined by Kim Macko 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 listed on slide 3, and those outlined in our latest forms 10-K, 10-Q and any 8-Ks, filed with the Securities and Exchange Commission. The information we provide about our products in 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 Elanco during 2018 and 2019 and present earnings per share as though the full disposition via the exchange offer was complete on January 1, 2018.

Now I'll turn the call over to Dave, for a summary of our Q3 results.

Dave Ricks {BIO 16504838 <GO>}

Thanks, Kevin, Q3 was another strong quarter for Lilly, as we continue to deliver robust results and execute on our strategy, which is launching new medicines, advancing our pipeline and driving productivity. Revenue grew 3% this quarter or 4% in constant currency, driven entirely by robust volume growth from our new products and international operations. Volume contributed 8% -- 8 percentage points of growth, despite sizable headwinds from the loss of exclusivity for Cialis in the U.S. and the withdrawal of Lartruvo. Excluding Cialis and Lartruvo, volume growth was an impressive 16%. Our newest medicines continue to be the engine of revenue growth and account for 44% of revenue this quarter.

We made good progress in productivity in Q3 as our non-GAAP operating margin was 28.6%, keeping us on track to meet our 2019 and 2020 operating margin goals. Compared to last year's quarter, operating margin was essentially flat, reflecting lower gross margin offset by prudent management of our operating expenses. We achieved milestones on several pipeline assets since our last earnings call, including the FDA approval of REYVOW for the acute treatment of migraine with or without aura in adults; the European Commission approval to expand Trulicity's label to include results from the rewind cardiovascular outcome study; the presentation of registration Phase 2 data for selpercatinib in non-small cell lung cancer and thyroid cancers and the presentation of overall survival data of Verzenio in metastatic breast cancer. Taltz also made impressive progress with its development program this quarter with the FDA approval of radiographic axial spondyloarthritis or axSpA along with its submission in Europe; submission of our non-radiographic axial spondyloarthritis in the U.S. and Europe, which represents our first-in-class opportunity in this indication and positive results from a head-to-head study in psoriasis versus guselkumab in IL-23 antibody. We remain focused on creating long-term value for shareholders as we allocate capital seeking external

innovation that will enhance future growth prospects while at the same time we returned nearly $1.2 billion to shareholders this quarter via share repurchase and the dividend.

Moving on to slide 5, you'll see more detail on key events since our last earnings call in July. I would like to highlight today's announcements regarding leadership changes and I want to congratulate and thank my long-time colleague Enrique Conterno, for significant contributions to Lilly. Enrique, has done an outstanding job leading Lilly Diabetes over the past decade really re-establishing our company as a leader in diabetes care with the broadest and fastest growing portfolio of medicines in the industry. Enrique, Lilly will not be in the strong position it is today without your leadership, your energy, optimism and thirst for excellence will be missed. I would also like to welcome Mike Mason as he assumes leadership for our diabetes business unit. Mike is a 30-year veteran with deep expertise and significant experience in our diabetes business. Mike is a patient focused leader with a track record of delivering results for Lilly and for patients in the U.S. and Canada. Under Mike's leadership, Lilly successfully launched both Jardiance and Trulicity in the U.S., becoming the diabetes market volume leader during his tenure. Since July 2018, Mike has led our Connected Care and insulin commercial and development organizations working to leverage technology to enhance insulin delivery and improve the user experience. Importantly, he has also led Lilly's efforts in building the most comprehensive suite of insulin affordability solutions in the U.S., including the Lilly Diabetes Solution Center to support people in need of less expensive alternatives for their medicines. Mike, it's great to have you join our senior leadership team.

And now I'll turn the call over to Josh to review our Q3 results and provide an update on financial guidance for 2019.

Josh Smiley {BIO 19888026 <GO>}

Thanks, Dave and good morning everyone. Slide 6 summarizes our presentation of GAAP results and non-GAAP measures, and slide 7 provides a summary of our GAAP results. Looking at the non-GAAP measures on slide 8, you'll see revenue increased 3% or 4% in constant currency. Gross margin as a percent of revenue declined 60 basis points to 79.6%. Excluding the impact of FX on international inventory sold, gross margin as a percent of revenue was 78.9%. On this same basis, our gross margin percent declined approximately 140 basis points compared to Q3, 2018 driven by the unfavorable impact of product mix due to Cialis, and the negative impact of price on revenue, partially offset by manufacturing efficiencies. Total operating expense grew 2% this quarter. Marketing, selling and administrative expenses declined 3% as our ongoing cost containment measures and lower litigation charges versus last year were partially offset by increased investment behind recent launches, consistent with our long-term strategy.

R&D expense increased 8%, reflecting higher development expenses for late-stage assets including selpercatinib and tirzepatide. Total operating income increased 3% compared to Q3 2018, as sales growth outpaced expense growth, driving operating income as a percent of revenue to 28.6% for the quarter. As our recent launches continue to drive revenue growth and headwinds from Cialis and Lartruvo, sunset in 2020, we expect additional operating margin expansion and bottom line growth. We are on track and committed to achieving our full year operating margin guidance of approximately 28% as well as our 2020 target of 31%. Other income and expense was expense of $25 million this

quarter compared to expense of $2 million in Q3 2018 driven by higher net interest expense, primarily due to the Loxo acquisition partially offset by investment gains.

Our tax rate for the quarter was 11.7%, which is a decrease of 320 basis points compared with the same quarter last year, driven primarily by a net discrete tax benefit related to the settlement of certain tax matters. At the bottom line, net income increased 5%, while earnings per share increased 10% due to reduction in shares outstanding from share repurchases.

In summary, in Q3 we again drove volume-based revenue growth and made progress on our productivity goals. In addition to continued solid execution, third quarter also featured impressive performance outside the U.S. as revenue grew 10% in constant currency driven by 12% volume growth. Examples of our ability to launch with excellence as Emgality and BAQSIMI are off to strong starts. The approval of the first medicine in a new class to treat acute migraine, submissions of new indications for our key growth brand in multiple geographies and important clinical data at major medical meetings from our late-stage portfolio.

Moving to slide 9, it outlines these non-GAAP measures for September year-to-date. While slide 10 provides a reconciliation between reported and non-GAAP EPS, you will find additional details on these adjustments on slides 24 and 25. Moving to slide 11, let's review the effect of price rate and volume on revenue growth. As mentioned earlier, worldwide revenue grew 4% in constant currency, driven by volume growth of 8%, partially offset by price. Foreign exchange reduced revenue growth by 1 percentage point this quarter. For the 16th straight quarter we delivered worldwide revenue growth despite major headwinds from patent expirations.

U.S. revenue was flat compared to the third quarter of 2018. Volume growth of 5% was led by our newer products Trulicity, Taltz, Emgality, Jardiance, Verzenio,and Basaglar. Excluding Cialis and Lartruvo, volume grew nearly 17%. Consistent with our 2019 financial guidance and in line with Q1 and Q2 results, U.S. price declined 5%. This quarter's decline was impacted by approximately 3 percentage points, driven by the net of higher rebates across the segments, offset by modest listed price increases and over 2 percentage points from increased funding obligations during the donut hole phase of Medicare plans. We anticipated approximately $200 million of impact for the year and our actual results are consistent with this projection. However, we are seeing the donut hole impact more concentrated in Q2 and Q3 than prior years and expect a smaller impact in Q4.

As our largest product, Trulicity of course, had a significant impact on the U.S. portfolios price decline. Trulicity's robust U.S. volume growth of 42% was consistent with first half trend and was partially offset by unfavorable pricing dynamics in the quarter, including disproportionate growth in lower net price segments driven by the access wins we had in 2018 and the increased volume associated with these wins throughout this year, increased funding obligations during the coverage gap in Medicare, rate harmonization due to payer consolidation and adjustments to our overall estimates for rebates and discount liabilities across various segments.

Combined, these factors had a negative impact on price in the quarter of approximately 20 percentage points. If we exclude these items, Trulicity price declined roughly 5% versus Q3 2018. Well, we don't typically give forward-looking product level guidance and don't intend to change that practice, I do want to provide some perspective on Trulicity over the coming quarters. We expect the Q3 negative factors to moderate substantially going forward as impacts from the donut hole diminished in Q4 and then will be in the base for next year's comparisons. Similarly, as we have driven rapid volume growth in government segments, including the VA and DoD between Q4 of last year and this quarter, we expect these segments going forward grow more in line with overall sales.

Finally, rate harmonization due to payer consolidation is now fully reflected in the base going forward. Given the absolute size of the Trulicity rebate and discount liability, we will continue to see quarterly adjustments to that liability. But as we have seen historically, these are difficult to predict, it can be both positive and negative. So taking these factors into account, we think Trulicity's underlying U.S. net price decline of roughly 5% in Q3 is more representative of what we expect to see in subsequent quarters. We have excellent access for Trulicity across all payer segments and anticipate that continuing in 2020.

Moving to Europe, revenue grew 8% excluding FX driven by 9% volume growth, partially offset by the negative effect of price. Volume growth was led by Trulicity, Olumiant, and Taltz. In Japan, revenue growth of 6% excluding FX was driven by volume with Verzenio, Cyramza, Trulicity, Alimta, and Olumiant as key contributors to the growth. We were negatively impacted by purchasing patterns in Q3 in Japan by approximately 4 percentage points, which we expect to largely recover in Q4. Revenue in the Rest of the World increased 15% excluding FX, led by 33% growth in China. The same information for our September year-to-date results is at the bottom of the slide.

As shown on slide 12, our key growth products were once again the engine of our worldwide volume growth. These products drove 15.4 percentage points of volume growth this quarter, reinforcing our confidence in achieving our 2020 revenue goals. Brands that have experienced loss of exclusivity provided a drag of 700 basis points driven primarily by Cialis. As expected, we have seen a rapid erosion of Cialis sales following the entry of generics in the U.S. market at the end of September last year. So we expect this impact to begin to normalize in Q4 of this year. Slide 13 highlights the contributions of our key growth products. In total, these brands generated over $2.4 billion in revenue this quarter, making up 44% of total revenue. Q3 sales of growth products were impacted by inventory burn in the quarter of approximately $70 million with U.S. Trulicity comprising approximately $40 million of that total.

Our diverse commercial portfolio of new medicines continues to drive growth and is well positioned in large and growing therapeutic areas. Within diabetes, Trulicity and Jardiance continue market leadership in the GLP-1 and SGLT2 classes, respectively. In immunology, Taltz continues to perform well in psoriasis and new indications in rheumatology present opportunities for additional growth. In pain, Emgality continues its impressive uptake exiting Q3 with a market-leading 46% share of market from new to brand prescriptions in the U.S. Within oncology, Cyramza growth has accelerated over the past year and we are excited for the newly released overall survival data to drive additional use of Verzenio.

Finally, I would like to highlight our newest launch product nasally administered glucagon, which is sold under the trade name BAQSIMI. BAQSIMI is an important new option for the treatment of severe hypoglycemia and unlike existing rescue therapies does not require reconstitution to administer. This is a significant improvement in user experience and exemplifies the type of innovation we strive to deliver to patients. The commercial uptake in the U.S. has been strong as BAQSIMI already has 33% of new to brand prescriptions. We believe this product has the potential to grow the overall glucagon market.

Slide 14 shows the year-over-year change in select lines of our income statement. Focusing on our non-GAAP results, foreign exchange rates had a net modest negative impact on revenue and a modest positive impact on gross margin, operating expenses, operating income and EPS. On slide 15, we provide an update on capital allocation. Aligned with our strategic priorities, between our business development activities, capital expenditures and internal investment in R&D, we invested over $11 billion in the first nine months of the year to drive our future growth. Additionally, we have returned nearly $6 billion to shareholders via dividends and share repurchases. We continue to prioritize investment in the pipeline through both internal and external sources.

Turning to our 2019 financial guidance on slide 16. You will see that we've updated our non-GAAP guidance to reflect an increase in our bottom line results for the year. Specifically, we are updating the range for other income and deductions to $50 million of income to an expense of $100 million, reflecting year-to-date gains in our equity portfolio, we are decreasing our tax rate from a range of 13% to 14% to 12% to 13% to reflect the net discrete tax benefit in the third quarter and we are raising our non-GAAP earnings per share range to $5.75 per share to $5.85 per share reflecting those two items as our operating performance expectations remain on track with our prior full-year guidance.

On a reported basis, the tax rate is expected to be in the range of 13% to 14% and earnings per share for 2019 is now expected to be in the range of $8.59 to $8.69 per share. We continue to progress towards our 2019 guidance and remain committed to delivering on our 2020 goals.

Now I'll turn the call over to Dan to highlight our progress on R&D.

Dan Skovronsky {BIO 15349505 <GO>}

Thanks Josh. Slide 17 shows select pipeline opportunities as of October 22nd. Positive movement since our last earnings call includes the previously mentioned FDA approvals for REYVOW and FDA approval for new indication for Taltz, the European Commission approval for Trulicity rewind and the submission of Taltz for non-radiographic axial spondyloarthritis. The U.S. submission of ultra-rapid Lispro, for type 1 and type 2 diabetes. The U.S. submission of Flortaucipir for uses of tau PET imaging agent in Alzheimer's, initiation of Phase III testing for mirikizumab in Crohn's disease, and the initiation of Phase 1 for 2 assets. In addition to the positive milestones, we delivered this quarter, we also announced disappointing results from the Phase III Sequoia trial, pegilodecakin in patients with metastatic pancreatic cancer. Pegilodecakin plus FOLFOX failed to show benefit in overall survival compared to FOLFOX alone and is difficult to treat a deadly cancer. While

this is a disappointing outcome for patients, we continue to move forward with pegilodecakin in lung and renal cancer, which we've always viewed as the key indications.

Moving to slide 18, since the last earnings call, we made progress on the number of key events; in addition to the previously highlighted approvals and submissions, Cyramza has been submitted for first-line EGFR positive non-small cell lung cancer in the U.S. As Dave mentioned in his opening remarks, the third quarter was an exciting one for our oncology portfolio as we shared promising registrational data for selpercatinib at World Lung and ESMO which showed impressive objective response rates and durability of response data along with low treatment related discontinuation rates across RET fusion positive non-small cell lung cancer, RET-mutant medullary thyroid cancer, and RET fusion positive thyroid cancer.

We're excited about the opportunity for this first-in-class and potentially best in class RET inhibitor to help patients with cancer. These are the kind of results, we were hoping for when we planned the Loxo acquisition and we are extremely pleased with the progress of Loxo since then. We were also pleased to share the results of the Monarch 2 study at ESMO showing that Verzenio plus fulvestrant delivered the largest median survival benefit to date in this setting, extending survival by 9.4 months. We also announced that Taltz demonstrated superiority versus TREMFYA in total skin clearance at 12 weeks for people living with moderate to severe plaque psoriasis and met all major secondary endpoints and Olumiant had a positive readout in atopic dermatitis in the third of five studies, which will support its global submissions; it continues to be a busy and productive year for our pipeline.

Moving to slide 19, last quarter we highlighted select Phase 2 opportunities, this quarter we'd like to highlight select Phase 1 molecules from our portfolio. As we continue to accelerate our internal discovery and development engine, by year-end we expected to have delivered more Phase 1 initiations in a single year than we have in any other year this decade. Importantly, these new Phase 1 entries represent a mix of internal discoveries from our own labs as well as external innovation that we have brought in through business development. We selected several Phase 1 molecule to highlight today.

Let me start with another molecule from the Loxo Oncology acquisition the BTK inhibitor LOXO-305, which is a next-generation non-covalent reversible BTK inhibitor that does not depend on interacting with the cysteine-481 residue. We started dosing patients in a Phase 1 -- 2 study earlier this year in patients with previously treated chronic lymphocytic leukemia, small lymphocytic lymphoma or non-Hodgkin's lymphoma. The unmet need in this space continues to grow. Since more patients are treated with chronic recurrent BTK inhibitors, more and more patients become resistant or intolerant to therapy; LOXO-305 was built to be potent selective and have well behaved human pharmacology; should these attributes present in the clinic as we hope, LOXO-305 could be an important new therapy for these patients.

As we announced in September. We plan to present data from the trial later this year. It will be a typical early clinical presentation from a dose escalation trial, including safety PK and any efficacy assessments that have been conducted. In neurodegeneration, last quarter we initiated with our collaborator AC Immune a Phase 1 study in healthy volunteers

for small molecule tau aggregation inhibitor. While still early in development, we're excited about this program and also about the target aggregated tau, of course aggregated tau along with amyloid plaque comprise the two pathological hallmarks of Alzheimer's disease.

Accordingly, we remain excited about our 2 Phase II programs aimed at disease modification in Alzheimer's disease. Zagotenemab, which is our anti-aggregated tau antibody and now especially tanezumab our entry PG antibody which is also in a Phase II trial designed to test efficacy in a carefully selected population. Both of these programs are now fully enrolled with tanezumab clearing an important interim futility analysis and we look forward to the final readouts for these trials in 2021. Moving to pain, earlier this year we acquired the rights to a novel small molecule somatostatin receptor type 4 agonist that's currently in Phase 1 as a potential non-opioid treatment for chronic pain. The clinical hypothesis here is that the known analgesic effects of somatostatin are mostly mediated by SSTR4, which is found in the dorsal root ganglia, a selective agonist for SSTR4 could therefore have an analgesic effect without peripheral somatostatin adverse effects.

We look forward to the internal readout next year to inform the potential progression of Phase II. Pain is the number one reason people go to physicians and if you look at the opioid crisis, there is still significant unmet medical need. There is more work to do here, and I'm excited we're a leader in this space with a number of interesting mechanisms now being tested in patients by Lilly.

Turning now to immunology, with 3 novel checkpoint agonists in Phase 1 with first-in-class potential BTLA agonist antibody CD200R agonist antibody and our PD-1 agonist antibody. These are all Immune resolution agents; when dampening down immune system with chronic immunosuppression, we're trying to potentially reset the immune system. These checkpoints exploit insights from immuno-oncology, but they work in a different direction as a checkpoint agonist, but the brake is on the immune system. BTLA is a novel checkpoint receptor that negatively regulates activation of BPDC and T cells; agonism at this pathway has the potential to provide a first-in-class treatment and our BTLA agonist antibody is currently being studied in Phase 1 b and lupus. CD200 is a key immune checkpoint that functions on both innate and adaptive immune system on many cell types involved in autoimmune skin disorders. Our CD200R agonist antibody is in a Phase 1 trial in both healthy volunteers as well as in atopic dermatitis patients.

Finally, we know that treatment of cancers with PD-1 inhibitors leads to a variety of autoimmune conditions; it's hypothesized that a PD-1 agonist with suppress activation expansion of lymphocytes leading to treatment of autoimmune diseases. Our PD-1 agonist antibody is currently in Phase 1. Each of these 3 opportunities represents novel biology, which we are among the first to explore with the potential for each to move into Phase II next year.

We also have an IL-2 conjugate license from Nektar therapeutics which preferentially stimulates expansion of regulatory T-cells; this potentially first-in-class opportunity is currently being studied in Phase 1b in lupus patients with Phase 1 data in healthy volunteers presented at EULAR earlier this year, which show the IL2 conjugate could

achieve robust expansion of Tregs. Additional Phase 1 studies in psoriasis and atopic dermatitis have been posted to ClinicalTrials.gov and are expected to start up before the end of the year. We expect to move to Phase II with this molecule in 2020.

Finally, I'd like to highlight two exciting diabetes programs. With our next generation injectable incretin GIP, GLP, glucagon, tri- agonist or GGG we're testing the hypothesis that adding glucagon to GIP/GLP will have more metabolic activity and stimulate additional weight loss. The initial Phase 1 study, to study the safety of a single injection in healthy participants and we're now studying multiple doses including dose titration. We expect this program to enter Phase II by late 2020 or early 2021; just like the hurdle for tirzepatide to enter Phase III was a meaningful improvement over Trulicity, the bar here will be a step change over tirzepatide itself. Additionally, our commitment to oral incretins has continued to increase as we advanced programs through development we seek to improve upon administration or efficacy. Our first oral incretin program which we licensed from Chugai last year is a small molecule non-peptide agonist of GLP-1 that entered Phase 1 earlier this year.

Our initial focus will be on PK with the expectation that it should be meaningfully better than a peptide as well as the PD response, which we should see even in Phase 1, this molecule could enter Phase 2 in early 2021; in addition to this approach, we're also pursuing dual GIP and GLP-1 receptor agonist peptides for oral delivery. These programs, which are designed to give tirzepatide like efficacy with a once-a-day oral peptide administration are also progressing preclinically and should enter Phase 1 next year. We look forward to tracking the progress of these assets over the coming years and we'll share additional pipeline updates on our next earnings call.

Now I'll turn the call back over to Dave for some 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 third quarter. We delivered robust volume growth of 8% driven by our key growth products and an impressive performance outside the U.S. We continue to demonstrate our launch capabilities and have a diverse portfolio of commercial products to drive future growth.

We advanced our productivity agenda controlling operating expenses while investing behind key commercial growth drivers and our late-stage pipeline. In addition, we made important progress toward our margin goals as the operating margin improved 60 basis points versus Q2, 2019 to 28.6%. We made important pipeline progress including the initiation of a new Phase 3 program with mirikizumab in Crohn's disease sharing new registrational data for Olumiant, Taltz, Verzenio, and selpercatinib submitting new indications for Taltz and Cyramza and receiving positive regulatory actions for (inaudible) and Trulicity. Finally, we returned nearly $600 million to shareholders via the dividend and completed $600 million of share repurchase as well.

We are proud of our strong business performance and excited about the opportunities ahead for the company. There has never been a more inspiring time to be working on

discovering new medicines and patients and healthcare providers are waiting the next wave of innovation. We have grown through the headwinds of Cialis and Lartruvo and we expect our strong business performance to continue driven by our newest products and a relative lack of patent exposure ahead and of course by the work of our scientists who continue to redefine with as possible for patients suffering from serious diseases.

Looking ahead we are focused on a strong finish to 2019 as we prepare for next year. This concludes our prepared remarks and now I'll turn the call over to Kevin to moderate the Q&A session.

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 or to a single question with 2 parts. Liya, please provide the instructions for the Q&A session and then we're ready for the first caller.

Questions And Answers

Operator

(Operator Instructions). Our first question is from the line of Chris Schott with JP Morgan. Please go ahead.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks very much for the questions, just two here. I guess first broader 2020 pricing question, you're seeing price erosion with the U.S. portfolio this year; is that a reasonable dynamic to expect in 2020 or we'll see some of these pressures start to ease as we get past the donut hole fill and some of these kind of one-time items with Trulicity that you mentioned?

And my second question was just elaborating a little bit more on Trulicity in terms of access and price dynamics in 2020, the pricing commentary in the prepared remarks is very helpful. I guess with the approval though of oral sema, are you seeing a more difficult payer environment here than in the past or any signs that payers are more aggressively managing the GLP-1 category. Thanks very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Chris. We'll go to Josh for the overall 2020 pricing and then to Enrique for your second question more specifically on Trulicity.

A - Josh Smiley {BIO 19888026 <GO>}

Thanks, Chris. I think as we look into 2020, just going back to the guidance that we gave in December of last year. So we were planning for sort of low-single digit net price erosion across the portfolio for the period of '19 and '20. I think that's what we see right now. We are going to see variability in the quarters as you mentioned, we've got donut hole and other things that are particularly I think acute in Q3 of this year, but I think the net as we

look and project into 2020, I think sort of low-single digit price decline is probably a fair place to be and that's very consistent with how we thought about 2020 goals and our productivity agenda and otherwise.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Josh, Enrique?

A - Enrique Conterno {BIO 16347230 <GO>}

So Chris when it comes to Trulicity coverage, we have unprecedented access. We are right now in the mid-90s from a coverage perspective, which is outstanding and we are projecting that into next year. It is too early for us to be able to say exactly how the discussions of oral sema are going with payers; of course, we'll learn more they basically get further into some of those discussions.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Enrique and Chris, thanks for the question. Next caller, please.

Operator

And the next caller is from Umer Raffat with Evercore. Please go ahead.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my question. I don't know how to ask my first one, but I'll ask anyways, given all the renewed interest. My question is on the A4 trial and I know you're using a super high dose of solanezumab tracked over 240 weeks. So my question is this, since this trial was fully enrolled about couple of years ago, what have we learned to date from any interim analysis that have been conducted and I ask because almost every patient in this trial has passed the week 76 follow-up. Thank you for any color on that.

And then secondly on glip and tirzepatide broadly. My question is what's the median duration on therapy real world on Trulicity currently and I ask about it relative to the 20-week titration being employed in Phase 3, and I'm also curious, is there any observations to date from blinded basis in the ongoing titration regimen. Thank you very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Umer. We'll go to Dan for the sola question and then Enrique to talk about what we're seeing today with the duration for Trulicity.

A - Dan Skovronsky {BIO 15349505 <GO>}

Thanks Umer for your question on solanezumab and the A4 trial. Of course, this is a trial of solanezumab as you pointed out for higher dose and it was tested in the original Phase 3 studies. But what's really interesting about this trial is that we're testing it in asymptomatic elderly individuals who don't have a diagnosis of Alzheimer's, but do have amyloid plaque in their brain. It's a four-year treatment that's planned and so we will get data on this trial

in mid-2022. So we just have to wait patiently for those results to see if silicon have efficacy in this very early population.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan, Enrique?

A - Enrique Conterno {BIO 16347230 <GO>}

So, when we look at Trulicity adherence, we and I think we've said this before, we tend to see better adherence with Trulicity than with other products. One of the things that we measure is refill rates. So, we measure the second refill rate, the fourth refill rate. Trulicity tends to have better adherence than the GLP-1 class, it tends to have better adherence than insulin, but also better adherence than orals, which is sometimes difficult to believe but the value proposition is that simplicity. Now it's is a complicated -- question when we look at medium duration of therapy, because we do lose so many patients in the first fill and in the second fill across all of the diabetes therapy. Just to give you a sense by the fourth fill, we are basically, Trulicity is basically in the 60s. What we basically see though is for patients that have stayed after the first year, we tend to lose about a third of those patients every year going forward after that. So that gives you certain sense of what is the adherence of Trulicity as you're thinking about modeling this.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Enrique, and Umer thanks for the questions. Next caller, please .

Operator

Next is the line of Terence Flynn with Goldman Sachs. Please go ahead.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the questions. Maybe two for me. Just I'm wondering your latest thoughts on the ongoing policy discussions in DC potential outcomes and impact to your business. And then as we think about Emgality for 2020, I know you don't give product level guidance, but you've been focused on the second phase of growth year into the primary care market, any update on the progress there as well as the initial European launch. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Great. Thanks Terence. We'll go to Dave for the policy question and then Patrik on Emgality in 2020.

A - Dave Ricks {BIO 16504838 <GO>}

Yeah, I wish I could provide a clear answer on the probable outcome of the policy debate in Washington, I think it's really unclear other than we probably know that the House Bill will probably pass the House completely on partisan lines and then we'll see from there. There are of course, a number of initiatives in the various Senate committees that the industry is for and Lilly certainly is for. If a version of those came together and passed both chambers; in general that would be I think a modest positive for us.

We see important to parties and important discussion that should happen providing out of pocket cap to seniors is important benefit and any changes that can possibly adapt the donut hole math and other pieces of the benefit, which we're talking about even on this call are helpful for products that are more commonly used for conditions like diabetes, so we track that closely. We're very engaged in this whole discussion, of course probably given the environment in Washington, the most probable thing is there isn't really legislation happening for some time, but -- point to note to investors, where we're promoting changes in particular the Part D benefit and affordability measures that can impact the pocket book at the pharmacy counter without throwing out the baby with the bathwater in wholesale change to the the U.S. system, which obviously be hugely damaging to the business model.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Patrik?

A - Patrik Jonsson {BIO 22620517 <GO>}

Well, thank you very much. We are very pleased with the overall performance of Emgality and we actually became the leader in NRx in Q3 and we have been that for more than 10 consecutive weeks right now and we are also closing the gap in terms of total Rx. When we look upon the access to Emgality, it is a best-in-class access with more of the 90% today in the U.S. and we are making steady progress in terms of the claims paid and we are today at three -- three-fourths of the claims being paid. And we are making steady progress in that regard as well. We still believe it's very early days for Emgality. We know that we have population in the U.S. of 6 million eligible for preventive treatment and all the 3 million of those are being treated today and year-to-date, we have approximately 100,000 patients treated with Emgality.

So we see a tremendous opportunity also moving forward, and also the prescriber base in U.S. is still limited, so only 15% of our customers are regularly prescribers of Emgality. So I think that signals very clearly the opportunity we foresee. We are also excited about the opportunity outside of U.S.; migraine is not a U.S. phenomenon. We had thought million patients suffering from migraine in EU and 9 million in Japan and only 2 million of those are treated in EU and 300,000 in Japan, it's still very early days and we have just received the regulatory approval from European Medical Agency and we are in pricing reimbursement discussion on accounted counter basis, but we believe that the opportunity for Emgality is big also outside of the U.S.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Patrik and Terence thanks for your questions. Next caller, please.

Operator

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

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey guys, good morning, thanks for the question. I just have a couple. Josh on the SG&A side, are there opportunities for more cost savings looking forward beyond what you guys

have talked about post the Elanco. So I'm just trying to get a sense for where the 3Q trends can be extrapolated and then Patrik another one on the migraine side. So I know obviously early in the REYVOW launch, but can you leverage the access you just mentioned with Emgality to help benefit REYVOW. I'm just trying to get a sense for the commercial synergies looking to 2020 and and with the CGRP space being a little bit more crowded, how has the pricing environment been so far. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

All right, thanks, Jeff. So, go to Josh for SG&A and then Patrik on the migraine.

A - Josh Smiley {BIO 19888026 <GO>}

Okay, thanks. Jeff, welcome back. On SG&A, yeah, I think if you look at what we see in Q3 and what we've been talking about relative to our productivity goals for 2020. We're pretty comfortable with the absolute level of investment we have behind our new launches. If you look at the last few Baqsimi, which I mentioned on the prepared comments and REYVOW for example, we're putting those into existing infrastructure and we'll get good leverage there. So we'll continue to invest behind our key launches. But I think the absolute level of SG&A with our ongoing productivity efforts to get more out of each of the promotional dollars we spend, we feel pretty comfortable with that, so you should expect modest to flat growth going forward on that line.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Josh, Patrik?

A - Patrik Jonsson {BIO 22620517 <GO>}

Well, thank you very much. We are also very excited with the approval of REYVOW and we are waiting for the DA to give overall assessment by January of next year and launching very early in 2020. Overall, we believe there is a significant need also in the acute treatment of migraine. We know that currently 5 million of Americans are being treated for acute migraine, but 35% to 40% of those don't respond or can't tolerate the triptans and approximately 15% of those are contraindicated for triptans, so that's why we believe it's really a tremendous opportunity of the 2 decades to launch a new oral treatment for acute migraine. We see some significant synergies with Emgality both in terms of access and the overall infrastructure and particularly being able to capitalize on the learnings that we have had with the launch of Emgality since the beginning of 2018, where we have rapidly been able to take a leadership position, not just in terms of access, but also in terms of of the NRx and closing the gap in TRx.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Patrik. Jeff. Thanks for the questions. Next caller, please.

Operator

Is the line of Tim Anderson with Wolfe Research. Please go ahead.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. I'd like to come back to 2020 and contracting and diabetes. I know you were asked this earlier, but you didn't give much of an answer, the stock down 5% today on a beat and raise. I think that reflects concerns about about whether you can hit your operating margin guidance in 2020. The outlook for diabetes, so specifically on diabetes you're in this window of kind of having an idea of where your coverage is going to be for Trulicity and Jardiance in terms of net live gains or lost and what the price concessions are. So, can you just hopefully give us a little more detail on how we should be thinking about Trulicity specifically and Jardiance as well going into 2020, because there have been changes in the competitive dynamics there.

Second question, just going back to Alzheimer's, it seemed like a couple of years ago, Lilly started to quietly pivot away from thinking that any monotherapy that's anti-amyloid would yield the benefit and you started to really go down this combination route, given what Biogen disclosed yesterday and your ongoing work in this area. Just how are you thinking about monotherapy in the anti-amyloid space and really anything you can offer, your impressions of the news yesterday would be helpful. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Tim. So we'll go to Josh for outlook for 2020 and then to Dan for the question on Alzheimer's.

A - Josh Smiley {BIO 19888026 <GO>}

Thanks, Tim. As we said in the opening, I think if you look at Trulicity and strip out the things that we see in Q3 that we say are concentrated in that quarter. We feel good as Enrique mentioned, feel very good about the access that we have now and the access we project into 2020 and as we said, you should think about Trulicity at a modest year-over-year price decline, which is really just a function of modest price increases and we like the price and the value that [ph]clips have in the U.S. today. So we'll do everything we can to preserve that and we feel confident as we head into 2020 that that's a very manageable dynamic.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Josh, Dan?

A - Dan Skovronsky {BIO 15349505 <GO>}

Yeah. Thanks, Tim For the question. Of course, with respect to the amyloid hypothesis and the Biogen data. I think there was a lot of thinking about this when they announced their utility, that the main question was whether or not there was evidence that if you removed significant amount of amyloid pipe from the brain. This could result in a slowing of cognitive decline, so everyone was sort of waiting to see with the very highest doses where there was high level of amyloid removal what would happen. So I think the data we saw yesterday, from that respect is an important indicator on the amyloid hypothesis. We've thought for some time that complete removal of amyloid from the brain could be the goal here, doing it in early in the right patients could be important and that underlined the design of our trial with (inaudible), which we said should be able to remove plaque more quickly and more deeply than anything else we've seen. So I think yesterday's news is reason to be a little more optimistic about that theory. And as I said before, we're

excited to see the results of that Phase 2 trial; with respect to your question on combination therapy, indeed we do think that combination therapy is an important avenue in Alzheimer's disease. I think we're the first and probably the only company to have tried a combination of two disease modifying therapies, unfortunately we had to stop that, one of the therapies was a base inhibitor, which proven not to be a productive avenue of investigation. But given that we have both tau and amyloid approaches, I think combination in the future is a very rational approach for Alzheimer's.

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

Operator

Next is Louise Chen with Cantor. Please go ahead.

Q - Louise Chen {BIO 21301405 <GO>}

Hi, thanks for taking my questions. My first question here is when you first gave your 2020 revenue outlook or your long-term revenue guidance, what did you assume for Skyrizi an oral semaglutide and how have those launches proceeded relative to your expectations there. And then second question is, how do you think the data readouts from ESMO impact your thinking on the commercial opportunity for Verzenio, is there more growth left in the U.S. and how much can your share increase with this positive data. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Louise. We'll go to Dave for the 2020 revenue question and then to Anne on more data on Verzenio.

A - Dave Ricks {BIO 16504838 <GO>}

Louise, thanks for the question. Of course, we set the 2020 guidance in the middle of 2016. So many of the products were facing competition from etc today were a twinkle in the eye of the inventors back then and including some of our own launches at that time. We set the guidance because we thought there was a distance between what the people who do your work and the company thought about the long-term prospects, not line by line, but looking at a portfolio of opportunities that existed in front of us, of course, our ability to predict any one competitive situation or product uptake for Lilly is not perfect, but at that time we did project that we would launch 10 medicines by the end of ' 19 in the first five years of that period and that because of the profound nature of those opportunities, we were confident we would find a way to grow the company; at that point, the pharma business 6%, Elanco a bit slower. We've actually raised that to 7% and I think we're closing in on achieving that goal despite the fact that probably how we predicted we get there is at the same way we have. But I think that was the nature of the exercise back then and I think we successfully closed the gap and understanding in terms of what the opportunity for the company to grow was during during that time, so we're proud of that achievement. If we look at the competitive threats we face across our big products, of course that are there.

I would just point out as well though that Trulicity volume growth in the U.S. was over 40% in Q3. That's in the face of a year and a half of Ozempic and that Taltz volume growth was

substantial as well in the face of the Skyriziand TREMFYA uptake and in both those cases, it's important to understand that there is far more growth opportunity left in the classes we're participating in than share erosion threat to our eyes. Final comment on all this because I know there's lot of interest in the Q3 pricing dynamics on Taltz and Trulicity most of those effects were determined early in 2018 and are now manifesting themselves in Q3 of '19 whether it'd be the donut hole law change, which affect both of them. The rates we contracted on in the commercial mergers that occurred in the payer space or the contracting in the case of Trulicity and what we knew were lower price segments, but a good volume and of course at the margin are highly productive for us to make sure patients in VA DoD, those segments can reach our products. So just to put a perspective on all that long-winded answer but thanks for the question and maybe Anne address.

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

Yes, I would be very happy to. So thanks Louise for the question and quarter over quarter Q3 US sales were up 19% since Q2 and Q3 monthly sales look very strong as well. So we do believe that we are seeing growth from the outstanding survival results that we released and we do hope that we all see some growth for the CDK 4/6 market, although it may be in the single-digit area; for us here at Lilly, this is a relaunch of Verzenio. So the top priority for our team is to ensure that doctors, particularly those in the U.S. are aware of these statistically significant OS data nearly 10 months of survival benefit and we'll work with them to share that benefit the patients can have from Verzenio.

And we do know that oncologists are data driven and we have extremely compelling data and a very strong commercial team that will ensure that we get the word out. So we do hope very much to increase our share of market, obviously not all of the competitors in this space have been able to demonstrate statistically significant results and so we'll make sure that that data is well communicated, particularly we're going to encourage physicians to identify patients that are likely to do worse. So, you probably saw that data that we released at ESMO on where the cancer recurred or when it recurred and those patients do particularly well on Verzenio with some very robust results. Again we see that as a differentiator as well from some of the competition.

And we do know that physicians and patients number one goal is survival and we've been able to deliver now, as I said nearly 10 months of a survival benefit, which is really remarkable in this setting. And I think really a bit of a game changer for this molecule. So we look forward to next year. And then just to comment a little bit outside the U.S. and additional OS's good growth in the US, we're seeing a great portion of our growth come from outside the U.S., particularly in Japan and we just got the updated data that in combination in first-line in combination of aromatase inhibitors, we have a 30% share now and in the second line in combination of [ph]Avastin a 45% share. So really outstanding work by our Japan team and a good growth there.

And then great work in Europe as well with continued uptake, strong patient uptake in UK, France and Germany and many countries now having reimbursement and often running. So, as we look forward to next year with Verzenio and continue to grow based on this we think very significant contribution to this important medicine.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Is the line of Navin Jacob with UBS. Please go ahead.

Q - Navin Jacob {BIO 20931208 <GO>}

Great, thanks for taking the questions. You gave a lot of color on Trulicity and the pricing dynamics there, just on Taltz. I'm wondering if we could get similar sort of color, specifically UNH recently excluded Taltz from its 2020 formulary. Can you help us understand how the access looks for 2020 as you go into those discussions. Do you see any pressure there from some of the other newer entrants? And second question on Jardiance, you have a couple of trials reading out over the next few years. The EMPEROR trials and heart failure. How are you thinking about that opportunity, are those trials meant to bolster the profile of Jardiance in the diabetes market or do you actually view the heart failure opportunities as a individual stand-alone opportunity. And if so, could you help us understand if this could be a blockbuster opportunity by itself and then associated with that wondering if the six-minute function tests are fileable by themselves. Thank you very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Navin. We'll go to Patrik for the question on Taltz and then Enrique for the question about Jardiance.

A - Patrik Jonsson {BIO 22620517 <GO>}

Well, thank you very much. Access continues to be our challenge in the field of immunology in the US, but we will continue to ensure that through a combination of Taltz clear access program and contract with payers that we continue to ensure that patients get the access to whenever they need. If we look specifically into 2020, we expect 2020 to be similar to 2019 and incrementally better in some areas, and we know that not all plans have just present benefits schemes for 2020, as we believe we are entering into 2020 we have positive momentum and with Taltz now replacing Cosentyx as a preferred IL-17 we've OptumRx on their core formularies, which is covering more than 14 million lives in the U.S. So in an essence we believe 2020 to be very similar to 2019. But we have some incrementally better areas.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Patrik. Enrique?

A - Enrique Conterno {BIO 16347230 <GO>}

So we do see heart failure for Jardiance as a significant opportunity for us. I think you described it as a blocks status type of potential, and I think that's right. Clearly, we do have a lot of opportunity for Jardiance in type 2 diabetes. So heart failure is on top of the [ph]double block better opportunity in type 2 diabetes. We do have when it comes to the six minute walk test, we have a read out later this year. You asked whether we believe that data would be fileable with the FDA and we believe that we can get that data on our label.

Clearly the outcome studies are also critical for us and they will be coming at the end of next year and then for first half in early 2021, so very significant opportunity for Jardiance and for patients.

A - Dan Skovronsky {BIO 15349505 <GO>}

And this is Dan. I could just also add in that we are studying Jardiance in chronic kidney disease and Phase III trial that will read out in 2022. Just another exciting opportunity there.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. Navin thanks for your questions and next caller please.

Operator

The next is Seamus Fernandez with Guggenheim. Please go ahead.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Thanks very much. So just a couple of quick questions, first for the diabetes market. Enrique can you just help us understand the mix of payers, how that might be changing from a Trulicity perspective in terms of the next incremental script gained. And then similarly, where is Trulicity gaining the most traction incrementally amongst physicians, is it now really the growth driver growing beyond the ENDO market and pushing into the primary care physician portion of the market.

The reason that I ask that is because I think the mix of payers is really important relative to the incremental acquisition cost for each script considering the competition from an oral drug obviously moving and seeking to penetrate the primary care market. The other question is really a kind of bigger picture question on business development. I think Dave, you've said in the past that the focus now that Lilly has launched several successful products in the market today is to really reload the Phase 2 and the Phase 3 pipeline. Can you just give us a sense of where your focus, do you feel like the current Phase 1 pipeline is sufficient to advance there or is the focus more so or equally on areas outside and maybe you can just give us a sense of where you're most excited about the science going forward. Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Seamus. We'll go to Enrique first for the question on Trulicity mix of payers and then Dave for your question on business development .

A - Enrique Conterno {BIO 16347230 <GO>}

Seamus, Trulicity continues to grow across all payers. So whether it's commercial or Part D, of course as we've highlighted, we had this proportionate growth in the VA and DoD and other types of payers that tend to be lower price. But as we look at the future, we do continue to expect growth for the product across all of the different payers. When it comes to endo vis-a-vis primary care, we do see the class continue to grow across all segments and in particular Trulicity has been growing quite a bit when it comes to

reaching more primary-care physicians. So a big part of the growth is just having more primary-care physicians try -- new try a GLP-1 and start using and adopting this important class and because of the simplicity of Trulicity, it is an ideal product for that.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Enrique. Dave ?

A - Dave Ricks {BIO 16504838 <GO>}

Yeah, thanks for the question on capital allocation in VD. You have a right that we see a significant investment in our own labs, in our own efforts is very important. And we've had good success. We can't comment on the Phase 1 starts this year as an example, but we aggressively want to complement that with outside opportunities really it all phases of development and across all therapeutic areas. Now, of course, our opportunities to add value and find value are not uniform across stages of development or therapeutic areas and so that does skew our work in our effort there.

But we are open-minded about all five of the key areas we operate in and all phases of development, where we can add value and find value, those are the most exciting and attractive opportunities. Of course, this year we did our largest acquisition ever with Loxo Oncology on the one hand and on the other hand you saw a nice tuck into our pain portfolio with the Centrexion deal is another. We don't come at this with any particular financial framework, other than finding value and of course valuations and biotech have dropped a little bit lately. So, that always helps the equation. They've been pretty high over the last 18 months prior to that. So we continue to look at all mechanisms, all TAs in all phases and probably because of the number of opportunities, I've said this before, you will see is active in oncology, that's where a lot of early stage biotech is and earlier because that's where more of the opportunities lie.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Next is the line of David Risinger with Morgan Stanley. Please go ahead .

Q - David Risinger {BIO 1504228 <GO>}

Yes, thanks very much. So I just wanted to go back to the target. So with respect to the 31% operating margin target for 2020 that was reiterated today the street isn't quite there. I don't think I think it's just a tad bit below 31%. What is your sense that the street is over projecting in terms of costs, i.e., where do you think the cost will be lower than what the street is currently assuming. And then with respect to the revenue target that was provided in the second quarter slide, are you still comfortable with that $23.6 billion figure for 2020. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. We will go to Josh for both of those questions.

A - Josh Smiley {BIO 19888026 <GO>}

Thanks, Dave. On the targets themselves and margins, I think if you look at how we've progressed since we've established those margins, what you've been seeing multiple hundred basis point improvements per year and this year we were clear in saying that wasn't going to be the case, because of the Cialis overhang that we faced this year.

So I think when we look at in 2020 and of course, everybody has got different, different models, I think it's a combination probably of where we see revenue and how we think we can manage cost again as I mentioned earlier on a prior question. We feel good about the overall SG&A investments that we have. So as we lose the overhang from Cialis and Lartruvo, the volume gains that we're seeing in the new product portfolio and the price that we're projecting gets us I think in a much better growth position on the top line with modest growth on operating expense line.

So again we're confident, we've reiterated, as you know we raised this this number a little bit, we reiterated every opportunity we have that we will get there. I think it's probably just a function of both top line and more modest increases in operating expense. But again, that is very much in the context of the competitive dynamics we face and with the large growth opportunities we have long-term, we are going to invest behind those. In terms of the revenue piece, I think the answer again is the same as you look at how the portfolios performing on an underlying basis this year where we're confident in the minimum number that we need to achieve in order to get to the 7% compound annual growth rate target that we've outlined.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Josh. Dave, thanks for the questions. Next caller, please.

Operator

In the line of Steve Scala with Cowen. Please go ahead.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you and Dave for investors who choose to be skeptical this quarter has provided things to point to, so you explained Trulicity and Taltz, but Basaglar and Alimta also fell short. The beat was tax rate driven as was the 2019 guidance raise, Enrique is departing at a not ideal time. So, why should we be confident that the weaknesses are temporary, the tax rate lowering will create a tough compare in 2020 since one time factors occur once and that Enrique's departure doesn't portend difficulty ahead in diabetes. So that's the first question.

And with the stock unusually weak this year and given your confidence in the outlook, why not take this opportunity to be more aggressive with share repurchase. Why isn't this a phenomenal opportunity. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Steve. We'll go to Dave for the first handful of questions and then Josh on the share repurchase.

A - Dave Ricks {BIO 16504838 <GO>}

Yeah. Great. Steve. Thanks for synthesizing the bare case so effectively there. We of course have an answer to all of those things. And honestly, I don't think there has been a more interesting and exciting time to be in this company or more optimistic time and we went through many of those reasons today. We are broad portfolio products that are new in a life cycle with Cialis behind us remembering that Cialis is a 6.0 growth headwind over the last four quarters, that's ending now coupled with the one-time price effects, which we went through today, which we really believe are substantially one time either a step-down on the big mergers with our payers or the one-year effect of the donut hole which falls disproportionately on companies like Lilly, who have retail oriented products and then we look ahead in diabetes. I have to be honest, I think the diabetes pipeline, the growth opportunities ahead whether it be with Jardiance or Trulicity were precipitated, has never been stronger for the company.

So I'll let Enrique answer the question on his timing, but I think he is leaving on top and there is another level to get to in Lilly Diabetes that's certainly how I feel I think of course every category we're in, we've talked about, we compete with companies, some of the bigger than ours. Some of them more focused, because we have more opportunities than the average company out there and that doesn't mean that every quarter, every line item we're going to nail our goals.

So I think we're honest with ourselves about that, but we have more than half a dozen products that get scale in a significant way and given our base of pharma revenue, I think that continues to offer a unique situation and then you couple that with margin expansion, which were convicted on as per the prior question and given our placement in the league table there, certainly we have upside on that one as the topline scales. I can't think of a better place to work in this industry, to be honest, we've got a great opportunity ahead. Now on share buyback, I'll let Josh address that, but certainly that has been our thinking. We've done aggressive share buyback this year as we think about sources of cash etc that's clearly on our list. And when we have that discussion with the board, I'm sure that will be key topic as we planned capital allocation over the coming years. Enrique you want to touch on your retirement. I think it's probably worth a mention here.

A - Enrique Conterno {BIO 16347230 <GO>}

Look I'm sad to be leaving and retiring from Lilly. We're very proud I think of the business that we've build in diabetes as good as I feel about building the business together with all of my colleagues, I feel even stronger about the bright future that diabetes has and Lilly has ahead. Just I think about Trulicity, Jardiance great momentum, leadership brands, but with important catalysts when it comes to Trulicity on rewind and the higher doses and when it comes to Jardiance of course heart failure and CKD on top of (inaudible) opportunity in type 2 diabetes, and I continue to feel very bullish about what tirzepatide could do on both the efficacy and the tolerability profile. So very exciting time for us in diabetes overall and I couldn't be more excited about the future of Lilly Diabetes.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you.

A - Josh Smiley {BIO 19888026 <GO>}

Thank you yeah, just a couple of points; it's Josh. On share repurchase. As Steve, just to remind everybody, we did $3.5 billion share repurchase in the first half of this year, we did 600 million in the third quarter and as you say, when we see opportunities on the margins to create value, we're going to be opportunistic in share repurchase. Of course, we want to be balanced here as we mentioned in the comment, we want to ensure we've got the capital capacity to invest in the pipeline and business development opportunities when we see them. But, yeah, you should expect that when we see outsized movements will to do what we can.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you, Josh. Steve thanks for your questions. Next caller, please.

Operator

The line of Andrew Baum with Citi. Please go ahead.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you, couple of questions please. In relation to tau you spoke about access for next year. You didn't talk about pricing net pricing. Perhaps you could talk to that, given it's predominantly a commercial market. I'm assuming the rebating we've seen which looks like 40% is only going to go one way, I note that your 25% higher rebate than consensus -- the Cosentyx and your net price on our calculations at least is down 16% year-on-year. So color on where it goes in 2020 will be helpful. And then second, again on net pricing in relation to Trulicity, we estimate that about 25% of Trulicity is Part D, based by volume, I'm obviously coming from point of view of trying to work out the contribution of the additional donut hole impact versus other factors, if you confirm how close we are to where it is, that would be very helpful. Many thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Andrew. We'll go to Patrik for the question -- Josh cover both.

A - Josh Smiley {BIO 19888026 <GO>}

Okay. Thanks, Andrew. On Taltz, (inaudible) the Taltz pricing dynamics are a little bit different than Trulicity as Patrik mentioned I think earlier as we've talked about in other calls, about a third of our prescriptions now, just given the access challenges we have are not reimbursed or Lilly ends up being the primary payer. So as we get incremental access, you see interesting price moves here. So we're happy to gain access in pay rebates for that volume because we're transitioning patients in some cases from free product to reimbursed product. That being said, there are other cases where the product may not be on formulary, but as we work through PA process and other things, we end up ultimately getting 100% reimbursement.

So I think as you look at that piece, you're going to see it will be a little bit more difficult in Taltz to translate prescriptions to net price. All that being said, I think if you look in the third quarter, the biggest dynamic we saw for Taltz on price was similar to Trulicity and that we saw a prior period adjustment and again this is just estimating the rebate liability and as we looked over the preceding 12 months as we get invoices in we had to make an adjustment there that in total when we look at the sort of in quarter adjustment, it was about 20 points of prices as well, so we don't see that going forward. I think as you look into 2020 as Patrik mentioned we've got some opportunities to gain some incremental access and that will show up at some price concession, but it's more than compensated for and volume. So we see a relatively sort of steady price but lots of things moving around under the water.

I think on Trulicity your estimates are good, about 30% of Trulicity right now is in Medicare Part D. We see that probably as pretty stable going forward and as we mentioned we see that the pricing environment on a contracted basis as being pretty stable as we head into 2020 as well.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Josh. Andrew, thanks for the questions. Next caller please.

Operator

The line of Damien Conover with Morningstar. Please go ahead.

Q - Damien Conover {BIO 15414079 <GO>}

Okay, great. Thanks for taking the question. I just wanted to follow up on the Taltz study that showed encouraging data head to head versus Tremfya at 12 weeks. And it looks like there is a 24-week secondary endpoint coming up and my question is, is there any data points coming up after 24 weeks maybe pushing into 48 weeks and I ask that because of the eclipse data that showed favorable data from Tremfya versus a different IL-17 but really didn't show the strong data until week 48 and I just wondering how you're looking at Taltz position against Tremfya in those sort of longer duration of treatment. And then maybe a follow-up to that is when you position the product for physicians, is the quick response or potentially a longer response more important from your marketing perspective. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Okay. Thanks. Patrik?

A - Patrik Jonsson {BIO 22620517 <GO>}

Well, thank you very much. We are extremely excited obvious first superiority to try out of an IL-17 over an IL-23 and we just got the data published a couple of weeks ago. So we are now in the phase of disseminating this data among healthcare providers in the U.S. and the rest of the world. The (inaudible) 12 weeks as you said and we shared or showed the superiority both in terms of onset of action and clearance; of the next data (inaudible) data cut will be at the week 24 and that is driven by the fact that we have seen also the IL-23 they peak in terms of efficacy pretty much at that time.

If we look into the key attributes, particularly among patients treated psoriasis, its onset of action, its clearance and its durability. And I think this was a third Phase 3 trial that we have to confirm that Taltz is superior both as [ph]similar STELARA and now Tremfya in terms of both onset of action and the end clearance, and we have 5 years data confirming the durability of efficacy as well, we really believe that there is a lot of good momentum with Taltz right now.

A - Unidentified Speaker

I would just add, you mentioned another IL-17, but we don't see these two IL-17 as similar and it's interesting to note that all our competitors who are doing IL-17 comparisons are choosing Cosentyx and not Taltz. I'm certain today, no one has actually compared any other psoriasis medicine to Taltz and I think that tells you a lot about the powerful efficacy that we deliver with this leading medicine.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Damien thanks for the questions and we'll go to Dave for the close.

A - Dave Ricks {BIO 16504838 <GO>}

Great. Well, we appreciate everyone's participation today and your interest in the company. As I said earlier, we've made meaningful progress thus far in 2019 and we're committed to our revenue and operating margin goals in '19 as well as in '20. While we continue to invest in our innovation-based strategy with a diversified and volume driven revenue growth from one of the freshest portfolios in the industry and complemented by a pipeline full of exciting opportunities, some of which Dan commented on today , we believe Lilly continues to be a compelling investment. Thanks again for dialing in. And please follow up with the IR team if you have questions we didn't address in today's call. Have a good day.

Operator

Ladies and gentlemen this conference is available for digitize replay after 11.15 AM Eastern Time today through October 23, of 2020 at midnight. You may access the replay service at any time by calling 1800-475-6701 and enter the access code of 472869. International participants may dial -- excuse me 320-365-3844 and use the same access code 472869. That does conclude your conference for today. Thank you for your participation, you may now disconnect.