Q2 2019 Earnings Call

Company Participants

- Anne E. White, Senior Vice President and President, Lilly Oncology
- Daniel M. Skovronsky, Senior Vice President and Chief Scientific Officer
- David A. Ricks, Chairman and Chief Executive Officer
- Enrique A. Conterno, Senior Vice President and President, Lilly Diabetes and Lilly USA
- Joshua L. Smiley, Senior Vice President and Chief Financial Officer
- Kevin Hern, Vice President of Investor Relations

Other Participants

- Andrew Baum, Analyst
- Chris Schott, Analyst
- David Risinger, Analyst
- Jason Gerberry, 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 and welcome to the Quarter Two 2019 Earnings Call. (Operator Instructions)

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

Kevin Hern {BIO 20557573 <GO>}

Good morning. Thank you for joining us for Eli Lilly and Company's Q2 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; and Enrique Conterno, President of Lilly Diabetes and Lilly USA; and Patrik

Jonsson, who is joining us for the first time as our incoming President of Lilly Bio-Medicines. 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 and 10-Q filed with the Securities and Exchange Commission. The information we provide about our products and pipeline is for the benefit of the investment community. It is not intended to be promotional and is not sufficient for prescribing decisions.

As we transition to our prepared remarks, 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 progress in Q2.

David A. Ricks {BIO 16504838 <GO>}

Thanks, Kevin. Well, it's an exciting morning for us here at Eli Lilly, and an important day for women around the world living with breast cancer, as we have just announced the positive results showing that Verzenio extends life for women with breast cancer in the MONARCH 2 trial. More on that in a few minutes, but first let me make a few comments on the overall performance in the quarter.

We continue to execute on our strategic objectives, focusing on launch excellence, progressing our pipeline and improving productivity and our capabilities. Second quarter revenue grew 1% and 3% in constant currency, despite the loss of U.S. exclusivity for Cialis late last year, and the impact of Lartruvo's impending product withdrawal. Q2 marked our 15th consecutive quarter of worldwide revenue growth. Our performance was driven by volume growth of 6%. Excluding the Cialis loss of exclusivity and the impact of Lartruvo, volume grew nearly 15% led by our key growth products, which accounted for 43% of the Company's revenue.

Q2 non-GAAP operating margin was 27.9%, representing a 250 basis point decline versus last year. This reflects a decrease in gross margin and increased investment in both our launches and our pipeline.

Operating margin improved by 170 basis points versus Q1 of this year, reflecting progress toward our margin goals for 2019 and 2020. We achieved milestones on several pipeline assets, since our last earnings call, including the FDA approval of Emgality for treatment of episodic cluster headaches in adults, the FDA approval of Cyramza as a single agent for patients with high AFP in second line hepatocellular carcinoma, and FDA approval of Baqsimi, our nasal glucagon for the treatment of severe hypoglycemia in patients with diabetes.

We're pleased to note that for all three of these approvals, Eli Lilly product represents a first-in-class opportunity within their respective indications. Additional milestones to highlight include the positive Phase 3 data for higher doses of Trulicity in patients with Type 2 diabetes, and the positive Phase 3 overall survival data for Verzenio from the MONARCH 2 study, which I mentioned earlier, and exciting milestones for Verzenio, differentiating this medicines from others in the CDK 4/6 class.

Also in partnership with Pfizer, we're prioritizing a potential U.S. submission of tanezumab in patients with moderate to severe osteoarthritis pain by Q1 2020, followed by submissions in EU and Japan. At this time, we are not planning regulatory submissions for moderate to severe chronic low back pain.

We continue to leverage our strong operating cash flow to augment our pipeline through external innovation, and return capital to shareholders. We announced our worldwide licensing agreement for a novel small molecule from Centrexion Therapeutics. That is currently being studied as a potential non-opioid treatment for chronic pain conditions. We completed the $3.5 billion accelerated share repurchase program announced in Q1, and we returned nearly $600 million to shareholders via the dividend.

Moving on to Slide 5, you'll see more detail on the key events since our last earnings call in April. In our continuing efforts to make medicines more affordable for patients, we launched Lilly insulin lispro this quarter at a list price of 50% lower than the current Humalog list price. While an important solution for patients, access so far has been limited. We will continue to work with peers to make this important solution accessible to patients.

I would also like to highlight our leadership changes. First, a sincere note of gratitude to Mike Harrington for his tremendous leadership and service to our Company. Mike, you've done a great job defending the Company and serving as a key adviser to our leadership team and our Board.

Second, I would like to welcome Patrik Jonsson as he assumes leadership for our Bio-Medicines business unit. Patrik is a patient focused leader with a long track record of delivering results in some of our largest markets. Under Patrik's leadership, Lilly Japan has climbed from the 17th ranked pharma company in Japan in 2014 to the number 6 ranking at the end of this year. We delivered the highest growth rate in Japan during that period of time, which include the successful launches of our key growth products. It's great J. Patrik joined the senior leadership team.

Now, I'll turn the call over to Josh to review our Q2 results and to provide an update on the financial guidance for the balance of 2019.

Joshua L. Smiley {BIO 19888026 <GO>}

Thanks, Dave. Slide 6, summarizes our presentation of GAAP results to 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 1%. Gross margin as a percent of revenue increased 81.0%. Excluding the impact of FX on international inventories sold,

gross margin as a percent of revenue was 80.2%, keeping us on track to achieve our long-term goals for manufacturing efficiency and profitability. On the same basis, our gross margin declined approximately 60 basis points compared to Q2 2018, driven by unfavorable impact of product mix and the negative impact of price on revenue, partially offset by manufacturing efficiencies.

Total operating expense increased 8% with marketing, selling and administrative expense increasing 7%, driven primarily by higher marketing investment to support the recent launch of Emgality in the U.S., as well as other key growth products. R&D expense increased 10%, reflecting higher development expenses for late-stage assets, including tirzepatide, our RET inhibitor and mirikizumab.

Total operating income decreased 7% compared to Q2 2018, driven by the investments I just mentioned, which put our operating income as a percent of revenue at 27.9% for the quarter. As our recent launches continue to drive revenue and operating leverage, we expect income growth, and improvements in operating margin, so we remain on track to achieve our full year guidance of 28%, as well as our 2020 target of 31%.

Other income and expense was expense of $32 million this quarter compared to income of $21 million in Q2 2018. So it's driven by higher net interest expense, primarily related to the Loxo acquisition. Our tax rate was 10%, a decrease of 670 basis points compared with the same quarter last year, driven primarily by a net discrete tax benefit associated with the resolution of US and foreign tax audits, as well as the timing associated with the impact of US tax reform. At the bottom line, net income declined 3%, while earnings per share increased 1% due to a reduction in shares outstanding from share repurchases.

In Q2, we made good progress aligned with our strategic priorities, as evidenced by driving strong volume based revenue growth despite significant headwinds from the loss of exclusivity of Cialis in the U.S. and the impact of Lartruvo, investing behind key growth brands such as Emgality, Verzenio, Taltz, Jardiance and Trulicity and continued pipeline progress, including three regulatory approvals, two submissions and positive Phase 3 readouts for two key growth products.

Slide 9, outlines the same non-GAAP measures for June year-to-date, while Slide 10 provides a reconciliation between reported and non-GAAP EPS, and you'll find additional details on these adjustments on Slides 27 and 28.

Moving to Slide 11, let's take a look at the effect of price rate and volume on revenue growth. This quarter, worldwide revenue grew 3% on a performance basis, driven by a 6% increase in volume, partially offset by price. Foreign exchange reduced revenue growth by 2 percentage points. For the 10th straight quarter, we delivered volume growth in each major geography. US revenue was flat compared to the second quarter of 2018. Volume growth of 5% was led by Trulicity, Taltz, Jardiance and Alimta. Excluding Cialis and Lartruvo, volume grew nearly 17% in the US with our diabetes products delivering over 24% volume growth.

Consistent with our 2019 financial guidance, US price declined 4% with nearly 3% driven by increased rebates in the Medicare Part D coverage gap resulting from the change this year in manufacturing funding from 50% to 70% of the (inaudible) Approximately 2% was due to unfavorable segment mix. The remaining 1% price favorability is a mix of modest list price increases, and favorable adjustments to estimates for rebates and discounts, partially offset by higher contracted rebate and patient affordability initiatives.

Going forward, we expect the changes in the coverage gap funding to continue to impact Q3 with less impact in Q4, and we still anticipate mid-single digit declines in US price for the full year.

Moving on to Europe, revenue grew 6% excluding FX, driven by volume, partially offset by the negative effect of price. Volume growth was led by Trulicity, Olumiant and Taltz. In Japan, revenue growth of 4% excluding FX was driven by volume, with Verzenio, Olumiant and Cymbalta as key contributors to the growth. Revenue in the rest of the world increased 12% excluding FX, led by 26% growth in China, on the same basis. At the bottom of the slide is the same information for our June year-to-date results.

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 650 basis points driven primarily by Cialis. As expected, we've seen a rapid erosion of Cialis sales following the entry of generics in the US market at the end of September last year. We expect this drag to continue in Q3 and begin to normalize in Q4.

Slide 13, provides a view of our key growth products. In total, these brands generated over $2.4 billion in revenue this quarter, growing to 43% of revenue. In addition to the sustained strong performance of Trulicity, Taltz and Jardiance, I'd like to highlight the performance of Cyramza which grew 19% in the US as our share of market doubled in second line lung. We look forward to continued growth as we launched the high AFP HCC indication in the second quarter, and expect to submit the first-line metastatic EGFR mutated non-small cell lung cancer in the US later this year.

We're excited to see Emgality continue to gain share, exiting Q2 at 41% share of market from new to brand prescriptions in the US, which is an increase of approximately 9 share points from where we exited Q1. As our best-in-class access continues to grow, we exited the quarter with paid script at approximately three quarters of total US scripts. We look forward to Emgality to continue its strong uptake in the US contributing meaningfully to sales in the second half of 2019.

Slide 14, shows the year-over-year change in select item lines of our income statement. Focusing on our non-GAAP results, foreign exchange rate had little impact on gross margin and a modest positive impact on operating expenses -- operating income and EPS.

Turning to our 2019 financial guidance on Slide 15, you'll see that we've updated our non-GAAP guidance to reflect the increase in our bottom line results for the year. Specifically, we're raising and narrowing the range for SG&A expense at $5.9 billion to $6.1 billion, reflecting continued investments in recent launches. We are lowering the range for other income and deductions to zero to an expense of $150 million, reflecting first half gains in our equity portfolio.

We are decreasing our tax rate from a range of 14% to 15%, to 13% to 14%, to reflect the net discrete tax benefit associated with the resolution of tax audits in Q2. And we are raising our non-GAAP earnings per share range to $5.67 per share to $5.77 per share, which reflects the Q2 discrete tax benefit as our performance expectations remain unchanged. On a reported basis, the tax rate is expected to be in the range of 14% to 15%, and earnings per share for 2019 is now expected to be in the range of $8.58 per share to $8.68 per share.

Slide 16, shows the progress we have made towards our 2020 revenue and operating margin goals. On the left of the slide, the midpoint of our 2019 guidance represents 5% revenue growth over 2018 in constant currency, despite headwinds from the loss of exclusivity for Cialis, and the impact of Lartruvo. With that performance in 2019, we would need to grow sales at 6% in 2020 to achieve the 2015-2020 minimum compound annual growth rate of 7% that we've outlined. As the headwind from Cialis LOE and Lartruvo abate in 2020, and our new products continue to scale, we're confident that we'll achieve that minimum revenue goal.

On the right, you can see that we've delivered a significant margin expansion since 2015, increasing from just under 20% to over 29% last year. Again as the impact of the Cialis LOE and Lartruvo diminishes this year, as our new products continue to scale we're confident we'll achieve our 2020 goal of 31% operating margin.

On Slide 17, we provide an update on capital allocation. Aligned with our strategic priorities, we spent over $10 billion in the first half of the year to drive future growth between our business development activities to capital expenditures, and internal investment in R&D. In addition, we returned nearly $5 billion to shareholders. As we look ahead in the second half of the year, we'll continue to fund the growth of our new key products and recent launches, invest in our pipeline, seek external innovation to augment our future growth prospects and return capital to shareholders .

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

Daniel M. Skovronsky {BIO 15349505 <GO>}

Thanks Josh. It's been an exciting quarter for R&D results, really capped off with the big news this morning that Verzenio's MONARCH 2 trial demonstrated positive efficacy at the interim analysis, improving overall survival for women with HR positive HER2 negative breast cancer. A bit more color on Verzenio and this important result in a minute. But first, I'll summarize some of the other R&D highlights for the quarter.

Slide 18 shows select pipeline opportunities as of July 25. Movements since our last earnings call includes the regulatory approvals that Dave mentioned earlier, the regulatory submission of empagliflozin in collaboration with Boehringer Ingelheim for type 1 diabetes, and the regulatory submission of Cyramza for first-line EGFR positive non-small cell lung cancer, the initiation of Phase 3 testing for baricitinib and alopecia areata, initiation of Phase 1 for five assets, including our oral GLP-1 receptor agonist, and the attrition of two Phase 1 molecules.

Moving to Slide 19, since the last earnings call, we made progress on a number of key events that we're monitoring for 2019, including the approvals, submissions and top-line disclosures that Dave and I have already mentioned. New this quarter, we've added the top-line readout for pegilodecakin Sequoia trial, which is a it is a Phase 3 trial in combination with FOLFOX, in second line pancreatic cancer. And we expect this event driven trial to read out later this year. You'll recall that ARMO had moved this program into Phase 3 based on limited data for Phase 1. This was driven by the high unmet medical need in second line pancreatic cancer.

As we've shared in previous updates, we still see lung and renal cancer as the key indications for this molecule. Later this year, we'll initiate a study in renal cell cancer, as well as a biomarker driven studies in lung cancer. In diabetes, we had a number of medical presentations at this year's American Diabetes Association meeting including ultra-rapid lispro for type 1 and type 2 diabetes, the Trulicity rewind CV outcome study, as well as several tirzepatide datasets. I'll share a few key takeaways from the ADA meeting.

Moving to Slide 20, I'll highlight that tirzepatide dose escalation study. The study demonstrated consistent efficacy with improved tolerability relative to the Phase 2b study that we shared at EASD in 2018. This is evidenced by a significant reduction in the treatment discontinuation rates shown here. The GI side effects that did occur were mostly mild to moderate, and were less severe than in the first Phase 2b study.

These results are encouraging, particularly because the dose escalation in the Phase 3 study was a slower stepwise design than it was tested in the Phase 2 dose escalation study. We believe tirzepatide is the opportunity to reset treatment expectations for patients for HbA1c and weight loss relative to current therapies. Five trials in the SURPASS program are already underway and we look forward to data readouts beginning in 2021.

Turning to Slide 21, you'll see summary data regarding the rewind cardiovascular outcome study for Trulicity. As a reminder, the patient population included and rewind was different from other CV studies for GLP-1s as observed by the notably lower rate of MACE events in the placebo arm depicted on the left. Studying a lower CV-risk patient population, established a high bar to demonstrate efficacy. And generated data in a population is more representative of diabetes patients seen in physician offices.

Despite the high bar for efficacy, Trulicity demonstrated clinically meaningful 12% reduction in MACE, while demonstrating safety consistent with prior studies. Equally impressive is the consistency of MACE results, which showed a benefit across a variety of measures, most notably, the pre-specified subgroups of patients with and without prior CV

disease. We expect the label to reflect the broad population we studied and we look forward to hearing from regulators on our submissions.

Moving to Slide 22. Last quarter, we highlighted the four big late phase bets we've made over the last 12 months. This quarter, I would like to highlight select Phase 2 opportunities. But first, let me start with some comments on Verzenio. Obviously, we've made exciting progress with this medicine, now generating additional data in Phase 2 and Phase 3, which highlight Verzenio's important differentiation versus other CDK 4/6 inhibitors.

When we previewed upcoming data readouts at our December 2018 Investor Meeting, we highlighted three important readouts that we expected over three consecutive years. We said we expected Phase 2 data in HER2 positive patients in 2019, Phase 3 data for overall survival for MONARCH 2 in 2020, and Phase 3 adjuvant data in 2021. We are pleased to share today that the first two of these readouts have occurred and both are positive. As per our press release this morning, the MONARCH 2 readout occurred earlier than expected and showed Verzenio extended life for women with metastatic HER -- HR positive, HER2 negative breast cancer.

This interim analysis was the first robust analysis of overall survival and required a stringent P value. While we had originally expected this trial to go to its final analysis in 2020, the results were strong enough to meet the endpoint at the interim analysis, making Verzenio the first and only CDK4/6 inhibitor in combination with fulvestrant to achieve statistically significant improvement in overall survival. We look forward to presenting these results later this year and working with regulators to submit this important new data.

In addition, we're announcing today that our Phase 2 trial and HER2 positive breast cancer was positive, making Verzenio the first CDK4/6 inhibitor show a positive efficacy in a randomized controlled trial in this HER2 positive population We work with regulators to determine the appropriate next steps. Also, we're pleased to share today that MONARCH plus, our Phase 3 study in China was stopped early due to efficacy. These data will support our upcoming submission for approval in China. Finally, I should say, we're still very much looking forward to receiving data in the adjuvant population. And our Phase 3 trial in this population is still expected to readout in 2021.

Now, let me turn back to the topic of ongoing Phase 2 trials, touching briefly on pegilodecakin, in addition to the Phase 3 pancreatic cancer results we now expect in 2019. The Phase 2 lung cancer trial Cyprus 1 and Cyprus 2 are on track to complete later this year and we expect data disclosures to come in 2020.

Moving to neuroscience, (inaudible) is our anti-tau antibody currently in a placebo-controlled study of nearly 300 patients. This study uses a tau imaging agent to identify early symptomatic Alzheimer's patients whose disease has not progressed beyond a potentially treatable state. Well, Alzheimer's is a higher risk area, we believe our molecule uniquely targets aggregated forms of tau, the key pathologic hallmark of the disease, and our trial design incorporates unique elements that will help us best learn of treatment with the tau antibody is a beneficial strategy for Alzheimer's disease. We look forward to seeing the data in 2021.

In addition, D1 Pam is our positive allosteric modulator that targets with dopamine D1 receptor. We previously shared some encouraging Phase 1 data that we're now studying this molecule in Phase 2 in the symptomatic treatment of Lewy body dementia, which includes patients with both -- dementia with Lewy bodies and Parkinson's disease dementia, focusing on improving attention and cognition. Based on enrollment, we expect data in early 2020. If we see a signal in the Phase 2 data, we're prepared to move quickly into symptomatic treatment of Lewy body dementia as well to Alzheimer's disease.

In immunology, we recently moved our anti-IL-33 antibody into Phase 2 development in patients with moderate to severe atopic dermatitis, an area of high unmet medical need. We're excited about the potential of this target and this molecule. This asset builds on our emerging immunology portfolio and we anticipate seeing data in the first half of next year.

Finally, I'd like to highlight two diabetes programs. First is our basal insulin-FC which is a next-generation basal insulin. Basal insulin-FC uses the same time extension technology that we used to create Trulicity, enabling convenient once weekly dosing. This asset has a potential to be the first weekly basal insulin, and could be an important new treatment option for people with diabetes. We anticipating reporting top line data next year.

Second, we have ongoing efforts focused on improving the delivery of insulin and improving patient outcomes. We know that more than half of people on insulin today are not achieving their A1C treatment goals. The ongoing Phase 2 efforts of our automated insulin delivery system are the first step in an iterative process towards a closed loop system that we believe has the potential to significantly increase the number of patients achieving their A1C goals. Pending positive Phase 2 data will move into Phase 3 in 2020 with a potential launch in 2021. We look forward to tracking the progress of these assets over the coming years and will share additional pipeline updates on our next earnings call.

Now, I turn the call back over to Dave for some closing remarks.

David A. Ricks {BIO 16504838 <GO>}

Thanks, Dan. Before we go to Q&A, let me briefly sum up the progress we've made in the second quarter. We delivered volume growth of 6% despite the continued erosion of Cialis due to generic competition and the withdrawal of Lartruvo. Key growth products Liberty impressive volume growth of 15% , which now represents 43% of our revenue. We made strategic investments in commercial and late-stage pipeline products to reach more patients today, and improve the standard of care in the future. Meanwhile we continued to progress towards our margin goals as operating margin improved to 170 basis points versus Q1 2019 .

We made progress with the pipeline this quarter. Including three regulatory approvals, along with the exciting MONARCH 2 overall survival readout for Verzenio. In addition, we moved one asset into Phase 3 development, while also advancing multiple assets into the clinic. Looking ahead, we're excited about the data disclosure for our RET inhibitor at a major medical meeting and subsequent submission later this year.

We also returned over $600 million to shareholders via the dividend, and completed our $3.5 billion accelerated share repurchase program. Finally, last week, the Senate Finance Committee released details of its plan to address drug pricing and improve patient out of fund cost for patients. This is of course just the latest in a continuing discussion in Congress and the administration, and it won't be the last word we'll hear from the Senate on this subject. I know there may be a lot of questions about this particular package, so let me make a few points here in the hopes of allowing our Q&A to focus on the solid Q2 results we delivered and the strong prospects for Lilly's future.

First, I want to assure investors that the industry has and will continue to focus on shaping this to be, guided by our core principles of encouraging and protecting innovation, fairness and transparency in the pharma industry and all healthcare, and lowering costs at the pharmacy counter for patients who use our medicines. While the Senate Finance Committee package advance some of these ideas, it falls short on many others. We'll be working with all stakeholders over the coming weeks and months to try to better align legislative proposals to our core principles.

I know many of you have and will continue to work to size the impact of these proposals on the industry and on patient care. So let me make a few comments here to help. We're reserving a more detailed numeric answer for a later time when there's more clarity and more uncertainty. The three parts of this package I'll highlight are the Part D redesign, resetting the 100% relate cap in Medicaid and capping list price increases in Part B and D. Pharma has already put out a public statement on the policy concerns from a patient innovation perspective, so I'll just focus on the practical implications here and assess the likelihood and the impact to Lilly. This strategy just follows.

A Medicare Part D redesign, which includes an out-of-pocket maximum beneficiaries seems, the most important and the most needed to be legislated in some form, and is a proposal, which would deliver savings to patients for use higher cost medicines with the addition of this out-of-pocket cap. Based on our current portfolio, we should have a neutral to positive impact on our diabetes portfolio, which currently is our primary exposure in the Part D benefit. But it would have a negative impact on our immunology and oncology business.

Removing the 100% rebate cap in Medicaid is the next most likely proposal in our view, as it was -- it has also shown up in a draft house legislation as well. The current finance version basis in the new cap at 125% in late 2022. Raising money for the government, but delivering no benefit to patients. In the near term, this would represent a larger headwind for us in the general industry, primarily due to our insulin business. Medicaid represents a little more than 10% of the U.S. Humalog and Humulin volume, so a 25% increase rebate would represent a moderate negative impact on our insulin revenue.

Finally, capping list prices, it was price increases at the rate of CPI inflation in Medicare Part B and D will perhaps be the less likely to be enacted proposal that we've seen. Medicare Part D is a market-based structure, which has worked quite well, coming in under budget, while expanding access to innovation for millions of seniors. We're concerned about the price controls this represents. And mechanisms already exist to limit price increases in these segments and contracting in Part D and the ASP reporting system

in Part B. While Lilly has already significantly moderated list price increases for our medicines, this policy if enacted we'd continue to encourage this kind of a moderation. Patient impact will be quite modest from this proposal, although accumulate through time as do the government savings.

Unfortunately, none of these proposals address the fundamental structure issue of the gross to net spreads, and this will remain a centerpiece of our advocacy over the coming months to remake the incentives for all actors and deliver substantial out-of-pocket savings to patients who use innovative medicines. I would note that as presented -- presently constructed, these proposals would begin to take effect in 2021 and 2022, and currently would have no impact on our 2020 guidance.

Longer term, in any case, we will continue to focus on volume driven growth through innovation. Across our Company, Lilly employees remain energized and motivated to progress the pipeline to bring innovative medicines to millions more -- million more patients who need solutions for different diseases. We are excited to execute our strategic priorities to deliver not only our 2019 and 2020 goals, but also to realize the long-term growth opportunity in front of us.

This concludes our prepared remarks. 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 two parts. Cynthia, please provide the instructions for the Q&A session. And then we're ready for the first caller.

Questions And Answers

Operator

Certainly. (Operator Instructions) And our first question will come from the line of Umer Raffat with Evercore. Your line is open.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my questions. First, I read the blog post with a lot of interest on Medicaid Max rebate caps. And my question is what's the dollar impact if that cap is raised to 125% and what's that dollar impact if there is no capital? I think this is one of those questions every investors is very curious about given the exposure here. So that's first. Secondly on R&D, I was curious on Cyprus 1 trial for ARMO which is due this fall. I understand it's an open-label trial, how would you set the investor expectations going into that readout knowing that IOIO [ph] of late, has been very disappointing? Thank you very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Umer. We'll have Dave take the first question and then Anne your second.

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

Okay. I appreciate the question. Although I was hoping to head most of these off in my prepared remarks, Umer. As I said the -- any version of a Medicaid M catalyst, we think is a regressive policy. It punishes companies by forcing us to underwrite state Medicaid, actually giving a rebate in excess of our list price. But policy issues aside, I think you're asking what the exposure of the Company is.

As I said this almost exclusively impacts our insulin portfolio across the Lilly medicines. And we are in the low teens in terms of total volume for Medicaid as a percent of that -- those businesses. So that would be the theoretical cap on the impact of those businesses. 25% of that is a smaller number related to insulin and insulin related to the total of the Company. So it's a concerning policy because of the nature of it. The absolute financial impact for the Company is capped in a way by the volume in Medicaid and the 25% with the phase-in is certainly a better version of a bad policy in any case, we advocate for leading to Medicaid MCAP at 100%.

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

Pegilodecakin, so it's -- Dan mentioned, we look forward to completing the studies and sharing that data at the beginning of Q1. We are particularly looking forward the results in Cyprus 1. So this is a patient population where we've added the Keytruda in high-expressers, so those are the PD-L1 over 50%. So positive data from those trials would trigger additional long trials, particularly -- potentially registration trials. We do continue to believe that the greatest opportunity for pegilodecakin is in lung cancer in the first line setting and then also in later lines whether following or combination with other IO agents.

And then the other area of great interest is renal cell cancer. Both lung and renal had encouraging data in the Phase 1 study. So as Dan mentioned, we do see this as a rapidly evolving landscape and then working on our plans to optimize peg in that setting. And so look forward to starting those studies at the end of the year, as well as biomarker driven studies in lung cancer and other tumor types. So more to come and Cyprus and pegilodecakin.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Umer. Next caller, please, Cynthia?

Operator

That will come from the line of Terence Flynn with Goldman Sachs. Your line is open.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the questions. Maybe first just would love some perspective on Trulicity growth in the second half given the dynamics you saw in the first half, there. And then can you help frame for us, the high dose data for Trulicity in the context of tirzepatide? And then my second question is on the LOXO-292. You mentioned you're going to have data presentation later this year. Just would love high level thoughts on kind of the durability and safety, tolerability, you're seeing to date. Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks. So we'll go to Enrique for the first question, and then Anne on that 292.

A - Enrique A. Conterno {BIO 16347230 <GO>}

Very good. Well, we are pleased with the performance of Trulicity. We got sustained strong volume growth. We saw a 41% prescription growth in the United States when we look at the second quarter of '19 relative to the second quarter of 2018.

As we look at that, our sales growth was below that. Clearly there was some price erosion. The bigger pieces of this price erosion were the high rebates that were somewhat offset by modest list price increases. And then about 7 points was the incremental funding of the donut hole, going from 50% to 70%. Clearly, when we look at relative to Q1, we did see good continued sequential growth when we look at volume.

I think importantly, I think the fundamentals of the business are very strong, as we look at both class growth of about 30%, and when we look at their share performance. We do have, as you mentioned, significant catalyst with rewind, and of course when it comes to the higher doses 3.0 and 4.5 milligrams for Trulicity. We are excited about the opportunities with both. When we think about tirzepatide, we sort of think of tirzepatide being in a completely different zip code when it comes to efficacy. That's why we utilize in the worse of resetting expectations of treatment for people with type 2 diabetes. When we look at both A1C and wait, so we continue to be very excited about that particular asset.

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

And then LOXO-292, thank you for that question. We will present as you said, an update on the registrational data in the second half of 2019 at one or more a medical meeting, and that's an advance the regulatory filing, which is on track for the U.S. by the end of the year. And we really do look forward to sharing that robust data set. It's now over 500 patients enrolled and it's rolled across tumor types with RET fusions or mutations. And we continue to be very excited about the profile as both a first and the best in class RET inhibitor. So LOXO-292 is highly potent and we've seen robust response rates and exciting emerging durability as well. And also a safety profile that doesn't carry the burden of cytopenia that can require costly supportive care interventions. So again enrollments continue to be strong. The LOXO team is continuing to do a fantastic job in this program. And so we're very much looking forward to sharing that data at upcoming meetings.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anne. Thank you, Terence. And next caller, please?

Operator

That will be from the line of Andrew Baum with Citi. Your line is open.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. First question, could you break down for us the initial versus subsequent lines of CDK 4/6 therapy for the entire market, and give us some idea whether you can use the MONARCH 2 data to cure formally status on that this commercial and Medicare plan for 2020?

And then second, if we take the inflation cap is something that will happen with the Medicare Part D. Is it possible that could relate concerns about rising insurance premiums to allow rebate reform to research as part of the proposal? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks. We'll go to Anne for the initial question and then Dave for the inflation cap question.

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

Well, thank you, Andrew. And you asked a really good question and thought about this carefully. So in a trial like this, the reason it's so difficult to show a survival advantage is because of patients crossing over. And the fact that we were able to demonstrate significance at a pre-planned interim confirms the strength of Verzenio, and we do believe differentiates our product. We do expect increased growth across all lines of therapy based on these results.

And importantly, we will certainly share this data with those making access and treatment decisions. As we've heard overall survivals, the most important outcome and most objective outcome as well, so this really verifies the importance of Verzenio to achieve that best outcome for patients. And we've heard repeatedly from patients that overall survival is the most meaningful one for both patients and the physicians who are treating them. And this is an incredibly devastating disease and women who are living with this disease want to do everything they can to be with their families as long as possible. So we're really glad to have delivered this result for women with metastatic breast cancer.

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

Thank you. Thanks for the question, Andrew. And I think you -- I didn't quite make it up. I think you're talking about the Part D CPI cap as it relates to the impact on the rebate reform score. Look, the Senate finance package, which is sort of the leading integrated package we've seen generates a huge amount of savings to the government, most of which does not go back to the patients. This is our primary issue with it. Even the reform within Part D that is on the table, the AF proposal pretty much pays for itself, but maybe generates a little bit of surplus action, really.

So the question we're posing to policymakers is how do we reinvest that? For yes, premium stability, premiums are already extremely low in Part D and have been stable for years, but more importantly, directly leave at the pharmacy counter more relieved than this package delivers with the various proposals. One of those is as you indicate is to go back to the idea of passing through some or all of negotiated discounts with seniors and indexing their co-payments, their deductible to net pricing not list. I think pretty much everyone is closely as you think this is a good idea, as you point out the issue has been the score.

Now, if we can find into Part D and make it in connection with the rest of the Finance Committee package, I think there is a huge potential to achieve all those goals. One could also look at phases, phasing it in or even partial rebate pass through stepping up through time. So all these ideas are -- ideas we've had as pharma that we're actively pushing on. And maybe the main thing about all this is, although this package, got a lot of ink, we're far from the finish line here and there'll be a lot of discussion, probably with policies we really don't like and some we like better like the one you're suggesting. And we'll do our best to try to shape this into something workable that addresses the fundamental issue, which is out-of-pocket costs for people who use innovative medicines.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. Andrew, thanks for the question. Cynthia, next caller, please?

Operator

That will be from the line of Steve Scala with Cowen. Your line is open.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. I have a couple. First on tanezumab, how would you describe your level of confidence that the 2.5 milligram can be approved in OA, why are you no longer a filing in chronic lower back pain and where does cancer pain stand? So that's the first question. And then secondly, AbbVie's IL-23 SKYRIZI seems to be off to a great start, and AbbVie specifically said they were taking share from IL-17. So just curious what you're seeing. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Steve. Dan will have you take the tanezumab question, and Josh, if you can handle SKYRIZI.

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

Yes. Thanks Steve for the question on the various tanezumab indications. In a sense, you're right, in the order that you put them in, which is that we sort of prioritize based on the data that we have and the overall benefit risk in each of those populations. So based on that as well as the unmet medical need in osteoarthritis, we've prioritized moving that forward with the regulators.

Overall, we wouldn't be proceeding with regulatory submissions and announcing that we're proceeding unless we had confidence in the overall benefit risk that this medicine provides in that population. That's based on the trials that we have recently disclosed. It's also based on the totality of the evidence and that's a decision that we've come to together with our partners.

At Pfizer, the chronic lower back pain we've decided not to pursue at this time for almost exactly the same reasons, given the unmet medical need in that population and the benefit risk in that population. Cancer pain is the third here in line and we don't have that

trial. It's taking a bit of time to read out and so it's hard to comment on what the benefits could be there given that we don't have that data yet.

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

Okay. On SKYRIZI, it's Josh. The launch is really in line with what we expected it to be. It's a good launch, if you look at it relative to Taltz and time normalize Taltz is a little bit better in terms of prescription trends. But in terms of what we see in the market place right now Steve first, we saw really -- we're pleased with Taltz's performance in the U.S. In Q2 we saw TRx volume growth of 61%, and really we see share growth. Really as we look at SKYRIZI, we see -- it looks like share coming primarily from the store, in the IL-20 -- 12 -- IL-23 class, maybe some from Cosentyx. But our growth continues and we feel good about the share performance that we're seeing. Of course for later this year, we're looking forward to releasing data on our head-to-head trial against (inaudible) and I think that will be an important competitive positioning for us.

So we -- overall, the biggest thing that we need to see is continued growth in the class. I think still majority of prescriptions are happening in the TNF class. So I think anything on the -- both of IL-17 and IL-23 classes are able to shift to the better more modern treatments is good for patients and it will be good for us.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you, Josh. Thanks, Steve. Next caller, please?

Operator

Go to the line of David Risinger with Morgan Stanley. Your line is open.

Q - David Risinger {BIO 1504228 <GO>}

Yes. Thanks very much. So I have two questions, please. First, Dave, you had mentioned that out-of-pocket costs for people who use innovative medicines are a challenge. But could you talk about what the industry is doing if anything with respect to such costs outside of Part B because the government's actions will likely only applied a Part D, that's where the government can affect drugs. And the industry has a major public relations problem with the majority of the population that is outside of Medicare Part D that struggle with out-of-pocket costs. So is the industry doing anything i.e. with the Chamber of Commerce or with major employer groups to try to change the dynamic of the out of pocket cost challenge?

And one final thing I'll just make a statement which is that it does seem that the industry has not been able to overcome the unfair treatment of drug coverage, i.e. the fact that people pay too much out-of-pocket relative to the out-of-pocket costs for other healthcare utilization such as physician visits, hospital visits, etc. So anyway, sorry for the long diatribe

but I did want to understand the industry's agenda outside of government reimbursement.

And then second, could you just talk about Lilly's evaluation of oral GLP-1 as a potential pipeline product opportunity? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks. Dave will have a -- Dave will take your first question, and then Dan will talk about GLP-1 oral pipeline.

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

Yes. Thanks, Dave for the question. A lot in there. But I think in general we agree that -- I mean, we need to improve the rhetoric in the -- around the industry. We're working hard to do that. But mostly we need to improve the experience of patients at the pharmacy counter. You correctly point out that a lot of the discussions about government programs, but for Lilly's business more than half our business in U.S. is commercially reimbursed in whatever we are doing there. That is an area of increasing focus for us. And I think there is probably four things that I would point to that we're both doing and ramping up.

The first is how we design and implement our own healthcare coverage. As a healthcare company, I think we can begin to shape the market by our own purchasing behavior. And I think we have -- that we are going through it here, one of the most progressive policies for our own employees as it relates to drug cover, including first dollar drug coverage on products like insulin and the way the deductible gets funded etc. And these are all physicians having years of experience, doing it. We're in a position to recommend to our peer companies as well as to insurance providers as best practice.

As you know, probably that -- recently there was an IRS ruling that is quite important maybe subtle thing that allows for the first time clarity around the question of whether medicines can be classified as a preventative treatment under HRA -- HSA designs and high deductible plans. And the answer from the IRS is yes, they can. So we will use that as I think, a new point to help those that are purchasing insurance products in the commercial market so they can design plans that are first dollar coverage zero-out-of pocket for important essential medicines, in particular in diabetes for us, but also other categories as well that affect millions of people.

Thirdly, a value-based pricing is something Lilly is taking a leading position on. Although it's been stubborn in government segments we're making enormous strides in commercial markets. And this -- well, it doesn't directly translate to the issue out-of-pocket costs at the pharmacy counter, I think it does allow us to both demonstrate the value of our medicines and share the risk and benefit of those medicines with self-insured employers. We're having a lot of success with this and I think it does begin to shift the discussion pretty dramatically around medicines as a cost versus medicines as a solution and that's important.

Finally, there are state-based efforts that are seeking to regulate the commercial marketplace. I think you'll see pharma and Lilly increasingly active in those debates,

Colorado being one of them that's out there. And as the playing field shifts from a federal debate during an election year where -- let's be honest very little will probably happen, the states may be a center for action in 2020, and we'll be ready to engage and advocate for policies that help patients with the innovative medicines there.

So a lot in my answer, but I think you pointed out, a good thing here which is commercial market matters for a lot of companies including Lilly, and we need to address those inefficiencies as well.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Dan?

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

Great. Thanks for your question on oral incretins. It's obviously an area of interest for us. And maybe speak generally about our strategy here, which is that we want to be able to offer oral incretin therapy that meets sort of one of two criteria. First, it could have a significantly improved bioavailability versus what's currently under development. And that's important because that will translate to more convenient experience for patients, more convenient dosing with more reliable efficacy.

The other option is to offer greater efficacy in an oral product than the currently available once weekly GLP-1s. So we're pursuing those two tactics with different approaches. So to get something that's very highly bioavailability you need to move to small molecules. And so here we have a program, which is characterized by molecule just moved into Phase 1 this quarter, we call the GLP-1 NPA or non-peptide agonist, which is the product that was invented by Chugai, and we partnered with them on that. So we're excited to see Phase 1 data from that. We'll quickly learn what kind of bioavailability we get, and that will determine how we pursue that project.

The other avenue to get better efficacy than currently available injectables really relies on next generation incretins. So these are by specific molecules like our tirzepatide GIP -- GLP where we are seeking to get the peptide to become orally bio-available. And we have a number of purchase to accomplish that and look forward to moving those programs into the clinic soon.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. And thank you, Dave. Next caller, please?

Operator

We will go to the line of Seamus Fernandez with Guggenheim. Your line is open.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Thanks very much. So just two very quick questions, first on Verzenio and HER2 positive disease. Can you just give us a quick sense of Lilly's definition of a clinically meaningful if the data registrational? And then just maybe give us an estimated market size or path to

thinking about the market size? And then separately, on Taltz, gross to net, can you just give us the gross to net currently? And given the Company's need to reposition the product for growth in RA, [ph] should we anticipate further price concessions in the next formulary negotiation cycle? Thanks a lot.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Seamus. Anne will review for the Verzenio question and then Josh will take the Taltz question.

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

Yes. Seamus, thanks for the question on the HER2 positive data. And as Dan mentioned in his opening remarks, we're extremely pleased to have a positive result in that study. And so -- as he mentioned, this is the first randomized controlled study to have positive results in HER2 positive breast cancer, and this has been a very difficult to treat population. And so finding opportunities for them to avoid chemotherapy has certainly been the goal of this study.

And so we do believe that the positive result in meeting the primary endpoint of PFS are clinically meaningful. And while I can't share the specifics of the data we will be presenting that in a scientific meeting later this year, we do believe that it's clinically relevant for patients, particularly those that want to avoid chemotherapy in this setting.

We do -- the next step, really is to discuss this data and that's our plan to discuss the data with regulators as we shared at the scientific meetings. So I can't comment any further at this time on regulatory strategy. On the market size, so as you probably know, this is about 15% to 20% of breast cancer, so this is not a - insubstantive market. So we do believe this is a significant opportunity as we go forward for these patients who have that particularly hard to treat type of breast cancer.

So again that put together with the overall survival data and the robust result that we had in the China registration study, I think all three just reinforce the strength that Verzenio brings. And again, the only CDK 4/6 that has continuous dosing, the only one with a monotherapy indication, and it's continued to help patients , particularly those of the poor prognosis. So I think we're very pleased to share these updates on Verzenio today.

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

And Seamus, on Taltz and price and gross to net really in the second quarter neither of those were major factors in terms of US growth. Our price and gross to net rates have remained pretty steady as we mentioned in Q1. About two thirds of Taltz's prescriptions right now in the US are reimbursed. And that really didn't change in Q2. We're pleased with the share performance in psoriasis. I think as you mentioned in the rheum space, we are looking forward to indications in axSpA, which we think will make us more competitive and open up a significant growth opportunity there. And we're focused on access and we would like to see that improve. But really in terms of price and availability today, not significant changes in the first half of this year.

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

Maybe just a comment to add to that. PSA is the indication on RA. I think we see -- the way we see this is, these additional indications actually will enhance our leverage in payer access discussion not erode it. So actually the -- I think it works the opposite way from the way your question was phrased. The more volume we can build and PSA, the more indications like axSpA we get, the more unique the product is and more leverage we gain. So I think we're optimistic about both the growth of the product, but also the pricing power in this market.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Seamus, thanks for your questions. Next caller, please?

Operator

We will go to the line of Chris Schott with JPMorgan. Your line is open.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks very much for the questions. First one is, there seems to be lingering investor concerns about Trulicity and GLP-1 pricing as we look out to 2020 and beyond to the launch of oral sema. Can you just give your latest thoughts in terms of how you see payers reacting to new entrants in the market, and should we be anticipating a more challenging pricing environment for Trulicity going forward? So that's the first question.

And second question is on tax. I think you mentioned some discrete items and a lower tax rate this year. Just any thoughts about how we should think about normalized tax rate for Lilly as we look beyond 2019? Thanks very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. So Enrique, and I'm going to Josh for the tax question.

A - Enrique A. Conterno {BIO 16347230 <GO>}

It's -- appreciate the question. I know we get this question often on Trulicity, and the outlook of pricing I'm unable to provide that. But I think it's important to think about the value that Trulicity is delivering today and the incremental value that we can deliver, as we think about rewind, as we can think about in the higher doses that Trulicity will be launching because all of that is basically additional value that the product will be providing. We think we have a strong foundation with the performance of the product. I'm not going to speculate on how Novo will price the product and what the potential responses from payers, maybe.

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

I think on tax rate, our prior guidance for this year on a non-GAAP basis was between 14% and 15% as we reduced that by a point, given the discrete tax benefits that we saw in the second quarter. I think from a long-term perspective, that 14% to 15% range is reasonable. One of the things, it's a swing factor here is the calculation around guilty and depending on where and how our income flows that's -- that again can move that a little bit. But we're comfortable in the sort of low to mid-teens as a sustainable rate given the tax structure that we have today in the US. So as long as that's maintained, we think we can maintain at somewhere in that range with again -- on any given year depending on where we're launching sales are moving, we could see a 100 basis point swing one way or another.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

We will go to the line of Tim Anderson from Wolfe Research. Your line is open.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. On Trulicity where is the Lilly Diabetes team expect that Novo's oral semaglutide source of business will come from in terms of drug classes? And when that product launches, do you think that will lead to a slowdown in the scripts for Trulicity that will be (inaudible) by investors, or is the class growth high enough such that Trulicity may not really budget all?

And then second question again on reform, sorry, Dave. I was surprised to learn from someone who is well-informed in this area that AARP was a key stakeholder in killing the proposed rebate reform because of their alignment with the drug industry where they supposed to get something like half of their funding. My question is, whether you think rebate reform still be brought back on to the table or is that permanently off the table?

A - Kevin Hern {BIO 20557573 <GO>}

Okay, thanks. So Enrique for Trulicity, and then Dave for the policy question.

A - Enrique A. Conterno {BIO 16347230 <GO>}

Yes. It's -- honestly it's very difficult to speculate given that we need to see when we think our source of business, we will need to see basically how Novo will price the product, what type of placement, what is the message and so forth and so on. I think what we see, though, I think just generally when we think about diabetes is that patients do tend to go to an oral first right as we think about orals. So right now I think the product that we basically have, that we are commercializing is Jardiance, which was an incredible evidence and incredible benefit. My sense is depend on how product positions -- this product, how they price this product, and that's going to be a pretty big barrier for them to overcome. I think we're extremely well positioned with the product. We're investing well behind it and we have a great partner on Boehringer Ingelheim to make that extremely successful.

A - Kevin Hern {BIO 20557573 <GO>}

Dave?

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

Yes. Okay. Thanks for the question, Tim. I think I guess we declare the experiment heading off questions in advance and prepared remarks that we missed our primary endpoint. Anyway. It is true, AARP was a strong opponent of rebate reform. We can all speculate why, but it's also true that the majority of their revenue, I think more than half comes from royalties from the Part D program. So easy to get cynical when you spent time in Washington.

That said, we still think it's a good idea. Is it possible to come back, well, probably in some other form. I think the broad based pulling of the (inaudible) gets harder because of the way the scoring happen and the politics around it. But as was mentioned by Dave Risinger earlier or perhaps it was Andrew, that inside of a Part D benefit redesign, the idea of patients linking out-of-pocket costs to something other than list price is a good idea. And there is a sliding scale, we don't have to go all the way. That could change the scoring and make it more affordable, and create a model for insurance design in the commercial market and other segments. So we're far from giving up on this idea.

And as you know, given a retail portfolio like Lilly's, with big gross to net spreads, over 50% on average across our portfolio, this is a single quickest and most efficacious way to save patients' money at the point of sale, and restructure the incentives of the payers to work on behalf of patients directly versus work on behalf of all beneficiaries, including non-patients, which is kind of how it's set up today. So we got a long way to go in this debate and this is an idea we have might go.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

We will go to the line of Louise Chen with Cantor Fitzgerald.Your line is open.

Q - Louise Chen {BIO 6990156 <GO>}

Hi. Thanks for taking my questions. So my first question is on tirzepatide. I wanted to ask you what you think or what level of GI side effects is considered acceptable by physicians? And then on your NASH and obesity product, how do you plan to differentiate your product from others in development, are those that are failed? And then my second question is on the CGRPs, the potential entry of these oral CGRPs. And do you think the prophylactic ones would interfere with the growth of the injectable CGRPs, and then what about the acute CGRPs if there is any overlap there with your products? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks. We'll go to Enrique for the question on tirzepatide and then Dan, if you want to talk about the CGRPs.

A - Enrique A. Conterno {BIO 16347230 <GO>}

We really have an excellent in market expert here because we've seen the success of GLP-1, so we know that with the level of side effects of the GLP-1 class, we can have significant success. We do believe that we are not going to be trading off. In the case of tirzepatide, we will get the additional efficacy and we believe that we will have a comparable side effect profile to the GLP-1 class.

When it comes to NASH and obesity, honestly we are bidding to be best-in-class product. We're not bidding to be first-in-class or we are thinking that we are going to reset the expectations of what's possible in both obesity and NASH with tirzepatide.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Enrique. Dan?

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

Great. Thanks for your question on the CGRP market and the potential impact of oral CGRPs coming to market. Of course, as you know and pointed out the injectable CGRPs so like our Emgality are approved and marketed for prevention for prophylaxis of migraine, whereas the initial indication for the oral CGRPs is likely to be in the acute treatment or a broader use of migraine.

I think there is a couple of questions about the oral CGRPs that are still outstanding, and probably first I would go to safety. One of the great things I think about the drugs like Emgality is the great safety data that we've been able to generate here. Remember, this is a relatively young and otherwise healthy population with somewhat chronic disease and so safety has got to be a key factor in choosing a medication in this population. There are questions about the safety of the oral class and we'll just have to see how that ends up with regulators.

I think there is also a bit of a mechanistic question here which there's just not data to address yet. So the question though is, if you've got chronic blockade of CGRP because patients on a preventive antibody already, and we know we pretty much maxed out on the dose response curve here. The question is whether adding an additional oral agent, will have any effect if it will even work as and part of and people are already on chronic treatment. So for that reason, we've looked for other mechanisms for migraine and part of that won't clash with CGRP antibodies, but rather are likely to be complementary. So we're excited about the potential that we can offer with lasmiditan and that's currently under FDA review. And I think will be an important new treatment in the broader space coming soon.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

We will go to the line of Jason Gerberry with Bank of America. Your line is open.

Q - Jason Gerberry {BIO 17237298 <GO>}

Good morning. Thanks for taking my questions. Just two questions from me. First on tirzepatide, just thinking about, absent the reporting of Phase III data, do you think we'll learn anything in the next 12 to 18 months as it pertains to the diarrhea side effect, and whether it's a GLP driven side effect? And then my second question just on the Olumiant detailed Phase 3 BREEZE data in atopic dermatitis, the IGA scores relative to dupilumab were a bit lower. So just sort of curious, based on the data we have so far in hand, how do you think Olumiant could be positioned in the atopic dermatitis market? Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Okay. Thanks. Enrique for tirzepatide, and then we'll go to Dan for the Olumiant question.

A - Enrique A. Conterno {BIO 16347230 <GO>}

Yes. My sense is I'm sure that we are going to be waiting for the Phase 3 trial so what we see basically on some of the Phase 3 trials for us to understand what these -- those titration actually delivers when it comes to tolerability. And as we mentioned, we feel very comfortable given the modeling and given the studies that we've done that we are going to have a product that has unsurpassed efficacy resetting expectations for A1c and weight loss, and at the same time a product that is tolerable and comparable to GLP-1s.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Enrique. Dan?

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

Yes. Thanks for the question on Olumiant for atopic derm. Just specifically comparing it to dupilumab, it just point out, obviously that it's tough to compare in this case, an oral medication with injected injectable biologic for atopic derm. I think Olumiant has some advantages in the repetidy [ph] of action and patients may like that. But really I think the important comparison here is versus other orals for atopic derm and there are none yet. So. we have the potential to be the first oral for atopic derm and I think that's encouraging. We've got more data to come here and we'll see how that comes out.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

We'll go to the line of Navin Jacob with UBS. Your line is open.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi, Thanks for taking my question. Just on Taltz, wondering if you could give any color on the underlying volume growth of the overall psoriasis market and psoriatic arthritis market? AbbVie is planning to double-digit underlying market growth in derm dynamic

that perhaps some (inaudible) missing, just wondering if you're seeing that level of growth. And then with regards to your SG&A line, it came in a little bit higher than expectations raised your guidance for the year. Over the next couple of years I know you're launching a bunch of products, wondering how you're thinking about that line, how we should be thinking about it?

And then finally with regards to capital allocation, we've seen several companies in this space do large deals and or just yesterday, a large spin-off. Any color on how you're thinking about your business whether there is any potential for restructuring that we may not be necessarily thinking about and or your continued interest in bolt-on M&A deals? Thank you very much.

A - Kevin Hern {BIO 20557573 <GO>}

Okay, thanks. So we'll go to Josh for the Taltz and SG&A questions, and Dave talking about the capital allocation structuring.

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

Okay, great. So first on the overall derm market, we're seeing low double-digit growth in total across the class. The IL-17s are course growing faster than that and I think we'd expect to continue to see with the launch of SKYRIZI, the IL-23s grow. And again I think that's what's probably most important is moving, as I mentioned earlier, moving patients from TNFs to the modern IL-17s and IL-23s . So we're looking forward to the data that will generate later this year on our head-to-head versus on (inaudible) And again we're focused on Taltz in psoriasis is on 100% clearance and acting fast and being durable. So we're looking forward to continued growth in that market.

As we move to SG&A, our guidance for the second half of the year really implies a pretty flat, absolute level of SG&A with the first half of this year. We're comfortable with that. As you look with our new product launches, we've got a lot of variable SG&A expense. We do a lot of direct-to-consumer advertising in the U.S., both television as well as digital. So we've got a good handle on how we pulse that investment and we've clearly in the second half of last year, as our new launches we're scaling, we're putting a lot of money behind them.

We've continued that the first half of this year, but in an absolute basis, we feel comfortable with sort of flat to moderate growth in SG&A as we look out over the course of the next few years. We think we're well invested behind our new launch products and mostly we'll see a mix of tactics, but a pretty good absolute envelope where we are now. And again that reinforces as I talked in the prepared remarks, so we look at operating margin for 2020 with the kind of sales growth that we'd expect headed into 2020. We do expect to see good operating leverage there and are very confident with our 31% operating margin target for 2020.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you, Josh. Dave?

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

Yeas. I mean on capital allocation nothing changes for us. I think we've said for quite some time, we don't believe in large scale merger activity generates value for shareholders. We still don't believe that. In terms of spin outs yesterday's news, we don't have such an entity to spin out. We had one in animal health and we executed that transaction. I guess of the thinking being similar in that we think human innovative pharmaceuticals is the business to be. And then it's what we do well and where we can generate a lot of value for all stakeholders, patients, society and shareholders if we execute.

So our focus in terms of capital allocation is really on funding organic R&D, and then looking outside for opportunities, bolt-ons mostly that would fall within the pipeline, building type exercise where we can add value where it fits within our therapeutic focus, and where we see value for us, shareholders and patients. So that what we've been focused on for some time. We had the Centrexion deal this quarter, LOXO in Q1, those types of things are what we're interested in and where our focus lies. And I don't see there's a change from even the past 10 years. So we'll continue on that path.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Dave. Navin, thanks for your questions. This ends the Q&A portion. I'll turn it over to Dave for the close.

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

Great. Thank you. We appreciate your participation in our call today and your interest in Eli Lilly and Company. As we begin the second half of the year, we reflect on the meaningful progress we made in the first two quarters and the opportunity that lies ahead on the balance of 2019. We are committed to our revenue and operating margin goals in 2019 and 2020, while we continue to invest in our innovation-based strategy. With a pipeline full of exciting opportunities and a diversified volume driven growth in the market, so it continues to be a compelling investment.

Thanks for dialing-in. Please follow-up with our IR team if you have follow-up questions that we didn't address on today's call. Hope everyone has a great day.

Operator

Thank you. And ladies and gentlemen, today's conference call will be available for replay after 11.15 AM today until midnight July 30, 2020. You may access the AT&T teleconference replay system by dialing 1800-475-6701, and entering the access code of 469634. International participants may dial 320-365-3844. Both numbers, once again, 1800-475-6701, or 320-365-3844, and enter the access code of 469634.

That does conclude your conference call for today. Thank you for your participation and for using AT&T Executive Teleconference Service. You may now disconnect.