Q4 2018 Earnings Call

Company Participants

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

Other Participants

- Alex Arfaei, Analyst
- Chi M. Fong, Analyst
- Christopher Schott, Analyst
- David R. Risinger, Analyst
- Geoffrey Meacham, Analyst
- Louise Chen, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Umer Raffat, Analyst
- Vamil K. Divan, Analyst
- Vineet P. Agrawal, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Eli Lilly fourth quarter 2018 earnings call. At this time, all participant lines are in a listen-only mode. There will be an opportunity for your questions, and instructions will be given at that time. As a reminder, today's call is being recorded.

I'll turn the conference over to Mr. Kevin Hern, Vice President of Investor Relations. Please go ahead sir.

Kevin Hern {BIO 20557573 <GO>}

Good morning. Thank you for joining us for Eli Lilly & Company's Q4 2018 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 Labs; Christi Shaw, President of Lilly Bio Medicines; Anne White, President of Lilly Oncology; and Enrique Conterno, President of Lilly Diabetes and Lilly USA. 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.

I will now turn the call over to Dave for a summary of our progress in Q4.

David A. Ricks {BIO 16504838 <GO>}

Thanks, Kevin.

We continued our strong performance in 2018 with fourth quarter revenue growth of 5%, non-GAAP operating income growth of 15%, and non-GAAP EPS growth of 17%. Newer pharmaceutical products, which represented 38% of human pharma revenue in the quarter, continue to be the driver of our worldwide revenue growth, led by Trulicity, Taltz, Basaglar, Verzenio, and Jardiance.

Highlights of our strong volume-based growth include 31% U.S. diabetes volume growth and 11% total pharma volume growth. This was achieved despite the significant headwind from the loss of exclusivity of Cialis in the U.S.

We continued to see our year-over-year expansion in operating margins. Excluding the effect of FX on international inventories sold, Q4 non-GAAP operating income as a percent of revenue increased by over 165 basis points, while investing in new product launches.

We made significant progress with the pipeline, including: the approval of Emgality for the prophylaxis of migraine in Europe; the submission of Emgality for the prevention and treatment of cluster headache in the U.S.; results from a Phase 3 study of tanezumab in patients with moderate to severe osteoarthritis pain; and the results of two Phase 3 studies of baricitinib in atopic dermatitis.

We also provided an update or announced the confirmatory Phase 3 study of Lartruvo in combination with doxorubicin for advanced or metastatic soft tissue sarcoma. This study did not meet the primary endpoint of overall survival, and there was no difference in survival between the study arms. We are now working with global regulators to determine the next steps for Lartruvo, and we'll present the announced data at an upcoming medical conference.

In terms of capital deployment, we continue to utilize our strong operating cash flow to access value-creating external innovation that will enhance our future growth prospects. We announced a definitive agreement to acquire Loxo Oncology, a biopharmaceutical company focused on the development and commercialization of highly selective medicines for patients with genomically defined cancers, which would add multiple first-in-class medicines to the Lilly portfolio and expand our oncology presence into precision medicines.

We also announced several other business development transactions, including an agreement with AC Immune to develop small molecule tau inhibitors for Alzheimer's and other neurodegenerative diseases. We announced an agreement with Hydra Biosciences to acquire all assets related to their preclinical TRPA1 antagonist program, currently being studied for the treatment of chronic pain, and an agreement with Aduro Biotech to develop novel immunotherapies for autoimmune and other inflammatory diseases.

In addition, we returned over $600 million via the dividend and announced a 15% dividend increase for 2019. We also repurchased $1.1 billion of stock.

I'd also like to provide an update on our plans for completing the full separation of Elanco. As we stated during our December investment community meeting, operationally we are ready to effect the full separation. Today, we are providing a timeline for the separation as well as the method we'll use to dispose of our remaining 293 million Elanco shares. Specifically, we plan to launch an exchange offer to Lilly's shareholders in the first half of this year to exchange our remaining Elanco shares for Lilly shares. The exact timing of our decision to launch this exchange offer will depend on market conditions, but the launch of the tender could occur as early as the coming days.

We're pleased with the market reception of the Elanco IPO and with Elanco's performance as a publicly traded company. Jeff [Simmons] and his team are well prepared to take the next step, and Elanco employees are excited about their future. We're proud of what we've accomplished together, and we share their enthusiasm for Elanco's future.

Moving to slides 5 and 6, you'll see more detail on the key events since our November earnings call.

Now I'll turn the call over to Josh to review the Q4 results and to provide an update on our financial guidance for 2019.

Joshua L. Smiley {BIO 19888026 <GO>}

Thanks, Dave.

Slide 7 summarizes our presentation of GAAP results and non-GAAP measures, while slide 8 provides a summary of our GAAP results. I'll focus my comments on our non-GAAP adjusted measures to provide insights into the underlying trends in our business, so please refer to today's earnings press release for a detailed description of the year-on-year changes in our fourth quarter GAAP results.

So looking at non-GAAP measures on slide 9, you'll see the revenue increase of 5% that Dave mentioned earlier. Gross margin as a percent of revenue increased 50 basis points to 76.6%. Excluding the effect of foreign exchange rates on international inventories sold, gross margin as a percent of revenue declined about 25 basis points.

Total operating expense increased 1%, with marketing, selling, and administrative expense increasing 3%, driven primarily by increased expenses to support our newer product launches, including the U.S. launch of Emgality, while R&D expense declined 2%. Total operating expense as a percent of revenue compared to Q4 2017 declined by over 190 basis points, benefiting from previously announced actions taken to reduce the company's cost structure, partially offset by investments in new launches in our newest late-phase pipeline entries.

Operating income increased 15% compared to Q4 2017, which put our operating margin at 25.1% for the quarter. And our operating margin excluding the effect of FX on international inventories sold was 24.8% of revenue, an improvement of over 165 basis points versus last year's quarter.

Other income and expense was expense of $4.8 million for this quarter compared to income of $111.9 million in last year's quarter, driven by approximately $100 million less in gains on investments. This reduction was due primarily to a large gain on the sale of an equity investment in last year's quarter and to a lesser extent mark-to-market reductions in strategic partnership or VC investments in public biotech companies in this year's quarter.

Our tax rate was 15.8%, a decrease of 440 basis points compared with the same quarter last year, driven primarily by the impact of U.S. tax reform.

So at the bottom line, net income increased 13%, while earnings per share increased faster at 17% due to a reduction in shares outstanding from share repurchases. Earnings per share also included a reduction of approximately $0.02 per share to reflect the non-controlling interest in Elanco.

Consistent with our performance throughout the year, we achieved significant earnings growth this quarter by delivering mid-single-digit revenue growth while carefully managing our operating expenses, leading to meaningful improvement in profitability versus last year.

Slide 10 details these same non-GAAP measures for the full year, where you can see the full-year impact of our strong top line growth and margin expansion as revenue grew 7% while operating expenses declined by 1%, which led to a 30% growth in non-GAAP EPS. Excluding the impact of FX on inventories sold, operating income as a percent of revenue for the full year was 28.4%, an increase of 470 basis points compared to 2017.

Moving to slide 11 provides a reconciliation between reported and non-GAAP EPS, and you'll find additional details on these adjustments on slides 25 and 26.

Moving to slide 12, let's take a look at the effect of price, rate, and volume on revenue growth. This quarter, foreign exchange reduced growth by 1 percentage point. On a performance basis, worldwide revenue grew 6%, driven by an 11% increase in volume, partially offset by price. Q4 represented the second straight quarter our human pharma business delivered double-digit volume growth.

U.S. pharma revenue increased 6%. Like last quarter, strong volume growth, which was 12%, led by Trulicity, Taltz, Basaglar, and Verzenio, was partially offset by price. Excluding Cialis, volume grew nearly 21% in the U.S., highlighted by U.S. diabetes products delivering over 31% volume growth.

While the U.S. pricing environment continues to evolve, our sustained success is driven by the execution of our volume-based growth strategy. U.S. price declined 6%, which was similar to Q3. Approximately 3 points of the U.S. price decline was driven by changes to estimates of rebates and discounts and disproportionate volume growth in certain government segments for Trulicity. Roughly 1 point of the decline was driven by new access and corresponding volume for Basaglar in Medicare Part D, which we didn't have in last year's quarter. We also had approximately 2 points of decline associated with increases in patient affordability and access programs for Taltz and Humalog, which also drove increased volumes. Looking forward to 2019, we remain comfortable with our projection of mid-single-digit declines in U.S. price, more than offset by increased volumes.

Moving to Europe, Pharma revenue grew 3%, driven by volume, largely offset by the negative effect of price and foreign exchange. This volume growth was achieved despite the loss of exclusivity for Cialis. Excluding Cialis, volume grew over 16%. This robust volume growth was led by Olumiant, Trulicity, and Taltz.

In Japan, pharma revenue was up 1%, with 9% volume growth largely offset by a drag of 8% from the impact of the biannual pricing cuts which took effect in Q1. Volume growth was driven by newer products, led by Trulicity, Jardiance, and Olumiant, with a significant contribution also coming from Cymbalta.

Our pharma revenue in the rest of the world increased 10% on a performance basis this quarter, led by volume growth from our diabetes portfolio, namely Humalog, Trulicity, and Jardiance, in collaboration with Boehringer Ingelheim.

Turning to Animal Health, worldwide revenue grew 6% on a performance basis this quarter, driven by higher volume. Higher sales of companion animal disease prevention and future protein and health products was partially offset by lower sales of products that are being exited and to a lesser extent declines in products for ruminants and swine and companion animal therapeutics. Slide 13 outlines the same information for our full-year results.

Now let's take a look at the drivers of our 11% worldwide volume growth on slide 14. Once again, our newer products were the engine of our worldwide volume growth. These

products drove 13.7 percentage points of volume growth this quarter, nearly identical to their contribution in Q3.

Brands that have experienced loss of exclusivity provided a drag of 450 basis points, driven almost entirely by Cialis. You may recall the generic versions of Cialis entered the U.S. market at the end of September last year. And as expected, we've seen a rapid erosion of sales. When excluding LOEs, the rest of our products posted Q4 volume growth of over 18%.

Slide 15 provides a view of our newer product uptake. In total, these brands generated over $2.1 billion in revenue this quarter, representing 38% of our human pharmaceutical revenue.

Our newer product growth demonstrates the successful execution of our commercial strategy. We're particularly excited about the launch of Emgality in the U.S. for the preventative treatment of migraine. While still early, the NBRx share gains we have experienced to date have been impressive. Combined with best-in-class U.S. payer access, we anticipate Emgality will be a meaningful growth driver going forward, demonstrating the promising future for our pain franchise.

Moving to slide 16 and continuing with our non-GAAP explanations, this quarter the effect of FX had a relatively minimal impact on our income statement, with a small negative impact on revenue and a small positive impact on operating income and EPS.

Turning to our 2019 financial guidance on slide 17, you will see that we've updated our non-GAAP guidance to reflect an approximate $0.34 impact of the anticipated Loxo Oncology acquisition, which we assumed closes this quarter. Additionally, the approximately $0.17 negative impact of Lartruvo's Phase 3 ANNOUNCE study results was offset by positive trends in our core performance business performance and an improved tax rate versus what we projected in December.

This updated non-GAAP guidance by line item includes: a decrease of $200 million on the top line, driven by the impact of Lartruvo, partially offset by the inclusion of Vitrakvi and an improved sales outlook across other products based on Q4 momentum; an increase of $200 million for R&D expense due to the addition of the Loxo Oncology pipeline; and a decrease of $100 million for other income and expense to a range of between $175 million and $325 million of expense, which is driven by higher net interest expense due to the Loxo Oncology acquisition.

As we stated during our investor call for the acquisition, the incremental interest expense reflects only a portion of the financing, as our 2019 guidance in December had already contemplated business development financing needs for roughly half the size of the transaction.

A decrease in our effective tax rate from 16% to 15%, driven by adjustments for U.S. tax reform. And this results in a decrease on our non-GAAP earnings per share range to $5.55 per share to $5.65 per share.

I would note that the revised guidance continues to include a reduction of approximately $0.08 per share to reflect the non-controlling interest portion of Elanco profits for the full year. The average of the 2019 non-GAAP earnings per share estimates for analysts who have updated their models since the Loxo Oncology and Lartruvo announcements is $5.55, and for those who haven't updated since our December meeting, the average estimates for those is $5.94.

Touching briefly on our updated GAAP guidance, the 50 basis point increase in the effective tax rate is due to certain Loxo Oncology acquisition and integration expenses not being deductible for tax purposes. In addition, GAAP earnings per share for 2019 is now expected to be in the range of $4.57 per share to $4.67 per share.

I'd note that currently the euro is slightly weaker and the yen and renminbi are slightly stronger than what we assumed in our guidance in December, but in total FX impacts are modest. We'll monitor FX movements and incorporate changes as appropriate in our quarterly updates.

Moving to slide 18, the numbers here should be helpful as you think about our business on a go-forward basis post the separation of Elanco. Our pharma-only expectations for 2019, first shared with you at our December investment community meeting, reflect: mid-single-digit revenue growth; relatively flat marketing, selling and administrative expenses; R&D growth to accommodate the Loxo Oncology acquisition and other Phase 3 investments; and operating income as a percent of revenue at approximately 28%, or 27.5% excluding the effect of FX on international inventories sold. We will provide an EPS range once we have executed the Elanco exchange offer and know the number of Lilly shares retired.

Although our updated full company EPS guidance is lower than our December guidance due to the Loxo Oncology acquisition, we still expect strong full-year performance, led by volume gains in our newer products. We remain committed to our innovation-based strategy and are making substantial investments in 2019 to bring forward our next generation of new products.

I'd also note that, despite the incremental costs associated with the Loxo Oncology pipeline and unexpected Lartruvo impact, we are committed to and confident in achieving our 2020 sales and operating margin goals.

As we move forward, we'll continue to prioritize funding for our existing marketed products, new launches and life cycle opportunities, in addition to replenishing our pipeline. We'll also continue to leverage business development to upgrade our pipeline and future growth prospects. And finally, we'll return excess cash to shareholders via increases to the dividend and share buybacks.

Now, I'll turn the call back over to Dave to review the pipeline and key future events.

David A. Ricks {BIO 16504838 <GO>}

Thanks, Josh.

Slide 19 shows select pipeline opportunities as of February 1. In addition to the pending addition of Loxo assets, movement since our last earnings calls include: the U.S. submission of Emgality for episodic cluster headache; the start of Phase 3 for tirzepatide in Type 2 diabetes; the start of Phase 2 for a once-weekly basal insulin and automated insulin delivery system, which is part of our connected care efforts that Dan highlighted at our December investment community meeting, and a new indication for Verzenio in prostate cancer; the initiation of Phase 1 testing for eight biologic entities across our therapeutic areas and the attrition of three early-stage molecules.

On slide 20, we provide a final tally on the key events we expected for 2018. As we reviewed in detail at our December investment community meeting, 2018 was a strong year for progress in our pipeline and in execution of our innovation-based strategy. And while we experienced a setback on Lartruvo in January, we enter 2019 with great momentum.

Slide 21 shows the early progress we've made on key events and we're monitoring for 2019. These include: the initiation of a Phase 3 study of empagliflozin in chronic kidney disease; results from a Phase 3 study of tanezumab in osteoarthritis pain; results from two Phase 3 studies for baricitinib in atopic dermatitis; and the previously announced and discussed Lartruvo study.

Now let me briefly sum up the progress we've made in the past 12 months and our priorities moving forward. In 2018, we delivered strong volume-based revenue growth of 7%, driven entirely by our new products, which accounted in the calendar year for 34% of pharma revenue. We continued our strong operating performance and our margin expansion of over 470 basis points excluding the impact of foreign exchange on international inventories sold. We've seen excellent progress in our pipeline, with our internal and external innovation investments yielding multiple approvals, submissions, and positive Phase 3 readouts, along with several significant first-in-class additions to our late-stage pipeline.

We completed a review of the strategic alternatives for Elanco. Through a well-received initial public offering, Elanco Animal Health became a publicly traded company. Elanco raised over $4 billion through the IPO and debt offering, the vast majority of which was provided to Lilly as consideration for the businesses Lilly transferred to Elanco in connection with the IPO.

We also returned approximately $6.5 billion to shareholders via the dividend and share repurchase, announced the pending acquisition of Loxo Oncology, and bolstered our early-phase pipeline and preclinical platforms with numerous business development deals. Moving into 2019, we remain focused on launching with excellence and continuing to replenish our pipeline.

Before moving to Q&A, I'd like to take a moment to comment on the latest news regarding potential U.S. healthcare system reform. The proposed rule that would eliminate

the safe harbor protections for rebates within the Medicare and managed Medicaid segments would represent meaningful change to the system.

While it's still a proposal, we see this as potentially accomplishing the following. First, this could be a win for patients, lowering their out-of-pocket costs at the pharmacy counter, with the greatest benefit realized by patients taking more highly rebated products such as insulin. Second, for innovative products and companies, the rule will shift the focus to demonstrating the value of our medicines and partnering with health insurers and systems to improve quality, outcomes, and lowering overall medical costs. Patients should directly benefit from price reductions and concessions in federal and commercial plans. Unfortunately, as you know, this rarely occurs today. Finally, this change could remove an artificial barrier to competition, creating space for innovation that addresses unmet needs for patients.

We continue to support making medicines more affordable and accessible to patients. Too often, the sick are subsidizing the well in our current system, and this appears to be a positive tool to address this issue. We are for improvements to the U.S. healthcare system like this, which appropriately balance patient affordability, market-based principles, and reward innovation. While I know you likely have many questions on this, I'm sure we'll continue to talk about this as more details emerge about the rule.

This concludes our prepared remarks, and now I'd like to turn the call back 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. John, please provide the instructions for the Q&A session, and then we're ready for the first caller.

Q&A

Operator

Certainly. First, we'll go to the line of Seamus Fernandez with Guggenheim. Please go ahead.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Thanks very much for the question. So just really quickly two, both on pipeline products. Just can you guys give us a quick sense of the expectations for how tanezumab and REMS program might be implemented and what that might look like in terms of its impact on the launch of that product?

And then the second question is just relative to the data that we got recently or at least the headline announcement for atopic dermatitis with baricitinib. Can you just give us a general sense of how you see those data competing in the market versus the existing product Dupixent? Thanks so much.

A - Kevin Hern {BIO 20557573 <GO>}

Okay. Thanks, Seamus. We'll go with Dan for the expectations for the tanezumab REMS program. Christi, if you want to weigh in on the potential commercial impact, and then to Christi for bari, atopic dermatitis.

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

Thanks for the question on tanezumab. Of course, we're excited to, along with our partner Pfizer, announce the data on the latest Phase 3 trial. We still don't have the full data package, of course, on this molecule on OA. As we said before though, we're very confident in the efficacy. We continue to see that replicate, and that's encouraging. The risk obviously we've been looking at is rapidly progressive osteoarthritis, RPOA, and the data that we continue to get I think is a very encouraging picture. This molecule, I think, if you take the context of the vast unmet medical need for chronic pain and the deficiencies with the existing therapies that are available, including opioids and NSAIDs, I think really this offers a compelling benefit.

So we have to wait and see what the next trials read out, particularly the long-term safety study. But if we can continue with the pattern of results that we've seen so far, I think we have great reason to be encouraged.

With respect to your specific question about post-approval REMS and things like that, I would just say it's premature to discuss that. Let's get the full data package and then move forward with the FDA.

A - Christi Shaw {BIO 19739271 <GO>}

And to what Dan is talking about, if you look at the commercial opportunity, the number of patients that are suffering from osteoarthritis is 27 million. And if you just look at the patients that are similar to what we enrolled in the study, 11 million of those patients are very similar, which is they've been on at least three different classes of analgesics, they've been – it's been over six years, they changed medications multiple times. So the unmet need, even in the most severe market, is extremely high. So as we look at the safety and REMS, et cetera, that high unmet need, the opportunity is still huge in the most severe patients.

Turning to atopic dermatitis, yes, we reported out positive results in terms of our atopic dermatitis meeting our primary endpoints. Recall, this is two of five studies, so we have three more readouts this year. That combination of studies will then support a global package.

Just to give you a little bit about the atopic dermatitis market, as you may or may not know, 54 million patients suffer from atopic dermatitis, 18 million of those moderate to severe. And if you talk to thought leaders, whether it's one-on-one or from the podium, they see this market like the psoriasis market was 15 years ago. And to be able to come to market with the very first oral is our goal, as these patients suffer and need new therapies.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Christi. John, next caller.

Operator

And that will be from the line of Steve Scala with Cowen. Please go ahead.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. I have two questions. Were the baricitinib trials in atopic dermatitis only positive in the 4-milligram arm, or was statistical significance achieved on the 1-milligram and 2-milligram cohorts as well?

And then the second question is the impact on 2019 P&L of the Lartruvo failure was not small. I appreciate there were reasons for this. But as we look to critical 2019 readouts, what can you tell us about their contribution to guidance? I am specifically thinking about the LOXO-292 LIBRETTO trial, the tanezumab safety trial, Trulicity AWARD-11, and Verzenio MONARCH PLUS trial. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. Christi, we'll have you answer the question on baricitinib, and then go to Josh for the guidance question. Thanks, Steve.

A - Christi Shaw {BIO 19739271 <GO>}

So as you look at the trial, it included three doses, 1-milligram, 2-milligram, and 4-milligram. 1-milligram did not meet the primary endpoints, but 2-milligram and 4-milligram did meet the primary endpoints.

As you look at the pain and the global assessment scores, the three primary endpoints, 4-milligrams did meet all of those, and 2-milligrams met two of the three. So as we look at those, we know in the atopic dermatitis market, the 4-milligrams is an effective dose and will be something that as we look at the total package we'll be submitting to FDA for approval.

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

Hi, Steve. It's Josh. On the guidance, I'd first say that for all of the R&D pipeline, as you mentioned, our R&D range funds and contemplates success in those categories. Obviously, with the Loxo addition, LOXO-292 is the primary driver of the $200 million R&D expansion in our line item guidance.

In terms of the top line, we look at all the opportunities and potential sales impacts and probabilize those, so they are contemplated in our range, although I would say most of the things that you mentioned really will have more of an impact in 2020 to the extent that they're positive.

As I mentioned in the upfront comments, even with the impact of Lartruvo coming out, we're confident in achieving our sales goal for 2020, which would be the 7% compound

annual growth rate for the Pharma business between 2015 and 2020. To achieve that, based on the guidance we're giving for 2019, that assumes a minimum growth of about 6%, and that's not dependent on any individual product launch or R&D readout at this point. We're confident with the number of launches that we're in the midst of now and the clinical data that are still accruing, we're confident that we can hit that number in 2020.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. John, next caller.

Operator

We'll go to Chris Schott with JPMorgan. Please go ahead.

Q - Christopher Schott {BIO 6299911 <GO>}

Great. Thanks very much for the questions. My first one was on your expectation for a mid-single-digit decline in U.S. price. I was just wondering, can you guys hit more granularity like you did in the 4Q about the drivers of that assumption? I guess what I'm really trying to get at here is should we be thinking about a similar dynamic like we saw in 4Q, where it's channel mix and patient affordability initiatives for the primary drivers of price decline or is this more about greater rebates and contracting pressures driving that erosion?

My second question was just about the operating margin targets as we think out to 2020 on Pharma. I think you're looking at about a 200 basis point impact versus prior guidance on Pharma for 2019. So maybe you can just elaborate some of the dynamics as we think out to 2020 and what we should be thinking about for the Pharma business there. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Great. Thank you, Chris. We'll go to Josh for both those questions.

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

Chris, first on the price decline for 2019, so one thing that we have that is new in 2019 is the Medicare donut hole expansion, the move from 50% to 70%. And that's got about a $200 million impact or close to 2 points of the mid-single-digit decline we'll have. So that's a new item in 2019.

Otherwise, we are seeing generally the same thing. We're seeing an increase in our patient affordability efforts. These are around Humalog. They're around new launches like Trulicity and Emgality, where we're very confident that those kind of impacts are positive in the long run. They lead the volume gains over time. We're seeing that certainly in Taltz right now. So we do expect a few points of drag there.

And then I think the rest is mostly going to be either mix or small unit declines, but nothing that – they're all related to maintaining or improving access. We obviously are always looking at diabetes as a big segment and one that faces a lot of competition, but

we're very happy with the access that we have going into 2019. And I don't think you'll see any big new headwinds from a pricing perspective.

As it relates to the operating margin targets for 2020, I think if you looked at the guidance we have for 2019, I think it's about – probably about 27% at the midpoint ranges. Remember, our guidance for 2020 now is when you take out Elanco is to get to 31%. Elanco when we take it out gives us about a point or so of benefit. So we're looking at about 300 basis points improvement versus our midpoint range this year to 2020. We think that's very achievable.

If you look at in 2018, we improved operating margin by about 450 basis points. We got there through mid to high single-digits top line growth and relatively flat expenses. As I mentioned, to achieve our minimum revenue growth, we need about 6% growth in 2020, which we feel good about. So mid-single-digit top line growth with good control and expenses gives us, I think, very good, just mathematically gets us there. So we're comfortable with the ability to achieve that minimum.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. John, next caller, please.

Operator

And that will be with Jason Gerberry with Bank of America Merrill Lynch. Please go ahead.

Q - Chi M. Fong {BIO 20313104 <GO>}

Hi. Good morning, everyone. This is Chi on for Jason. Thanks for taking my questions. I have one on pricing and one on Emgality. First one, can you give a little bit of color on how you think about the impact of Part D rebate reform on exclusive contracting, specifically on products with high (34:51) treatment? I'm just curious, does the company see an end to exclusive contracting if rebates are taken broadly away, or does Lilly believe the lower net cost provider will win the exclusive contract?

Second on Emgality, I'm curious to know how you think about the puts and takes for the progression of Emgality over 2019. Is Lilly's focus on primary care the reason that you might be lagging competitors in this space given neuro and head especially for early adopters? And if you could simply comment on the Emgality paid prescription rates a little, how it compares to the average of 50% right now, that would be great. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Okay, thank you. We'll go to Enrique for the question on Part D rebates and then Christie for Emgality.

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

I'm not sure that I understood the full question. But at this point in time, I think as we look at the status quo, we basically see the continued trends when it comes to exclusive contracting. As we all know, mid-term insulin is already contracted that way. And we see

basically trends where most payers are trying to restrict utilization, maybe have fewer products extract rebates and concessions. Clearly, right now there's some uncertainty when it comes to the new proposed rule, and we really need to see how that is going to play out. I won't be able to speculate at this time.

A - Christi Shaw {BIO 19739271 <GO>}

And on Emgality, we're so excited with the number of patients that are being helped by the CGRP agents. We expect probably 6 million patients to be eligible.

If you look at Emgality specifically in your questions, we launched in October, obviously, so we just have a couple of months of data. But right now, what we're seeing is similar, that our paid subscriptions are at about 50%. The marketplace splits up. About a third of the prescriptions come from primary care, a third come from neurologists, and a third come from mid-levels. So this very much will be an expansion into primary care beyond neurologists as well.

Specifically looking at Emgality performance, we ended the year, even though we launched late, at 20% NBRx, and we're currently looking at 26% already in January. So as you look at these launches, we just launched our direct-to-consumer TV ad campaign this week. We know that Lilly has very strong consumer activation relative to our competitors. We know that we have a drug that has not just demonstrated 50% improvement, but 75% and 100% reduction in monthly headaches that our competitors don't have, as well as quality of life. And we have the unique platform and device that Trulicity uses that we know over 1 million patients really like. So we're very bullish on both the market and on Emgality's ability to compete.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Christi. John, next caller, please.

Operator

That will be Louise Chen with Cantor. Please go ahead.

Q - Louise Chen {BIO 21301405 <GO>}

Hi, thanks for taking my question. My first question here is how long do you think it will take for Trulicity sales to benefit from your REWIND presentation at ADA, and what type of uptake do you think we should see after that?

And then secondly on the market opportunity for lasmiditan, just curious how you think about it now in light of the injectable CGRPs being approved and the potential for oral CGRPs to come to the market. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. So Enrique will take Trulicity, and then Christi will handle the question on lasmiditan.

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

Clearly, Trulicity is on an outstanding run right now and benefiting from a huge growth of the GLP-1 market. If anything, we are seeing the GLP-1 market accelerate from already very high levels, growing at nearly 30% on a year-on-year basis. Importantly, in the market, Trulicity has continued to perform well, and we've been able to gain share, in fact, over five share points since the launch of Ozempic.

Now as we look at REWIND, clearly we see this as a critical trial and data set that's going to benefit patients. The big impact is when we basically start promotion of this important data. And I think it basically solidifies I think the bright future that Trulicity already had. We expect that impact of course sometime in 2020, once we get the FDA action on the new label.

A - Christi Shaw {BIO 19739271 <GO>}

And then on lasmiditan and how it will play in the marketplace, we will have some regulatory action this year, so we're looking forward to that. If you look at the marketplace kind of how we look at it, with the 36 million patients who suffer from migraine, there's about 16 million of those that are diagnosed and 6 million that suffer from acute migraines and are taking therapy. And that is overlapping only somewhat with the prevention market.

So as you look at prevention CGRPs versus acute use, there's obviously a huge need for both distinctly. And CGRPs also obviously don't clear 100% of all patients of their migraines. So we see the use obviously may overlap there. And we think lasmi has a really great positioning versus the oral CGRPs. If you're taking a preventive CGRP, you may want to look at a different mechanism if you have to add to that. And then if we look at the acute marketplace, so many patients have fallen out of the market because of lack of efficacy or they can't tolerate the safety, so lasmiditan will be a great option for them.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. John, next caller, please.

Operator

That will be from Alex Arfaei with BMO Capital Markets. Please go ahead.

Q - Alex Arfaei {BIO 15433937 <GO>}

Great, good morning and thank you. Verzenio was notably below our expectations. You mentioned buying patterns in the U.S. impacted this. Could you please quantify the inventory impact and your latest long-term expectations for this product given the apparent slowdown in the CDK4/6 market?

And just as a follow-up, a bigger picture question on your operating margin. I'm just trying to look past 2020 here. Historically, you've invested more in internal innovation as opposed to external innovation. And with that higher R&D, your operating margin was

relatively lower to your peers. Now that you seem to have a more balanced approach with increased contribution from acquisitions, as your top line grows in the mid-single digits, is it reasonable to expect that Lilly can get to mid-30s operating margin? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Okay, thank you. We'll go to Anne for the question on Verzenio and then Dave will take the question on operating margin post-2020.

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

Thanks, Alex, for the question. So we saw about $4 million in inventory impact in 2018. As you mentioned, we are seeing flattening in the CDK4/6 market as penetration has occurred. With Verzenio, our focus is clearly on execution to drive new trial of Verzenio and increasing our share of market.

On a positive note, we're encouraged that we're seeing high conversion rates, with over 50% of physicians who trial Verzenio moving on to write additional prescriptions. We're also really looking forward to the launches outside of the U.S. So we've launched in Japan and in several countries in Europe, and the uptake has been strong as well. In particular, what we are seeing is good uptake in patients with a poor prognosis. And so that will be patients with mitral disease or liver metastases. So we're also driving execution in there. So we have hope for continued growth for Verzenio as we really focus on a strong year of execution across the globe.

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

As it relates to margins and long-term R&D strategy, it's a good question. I know there's a lot of appetite for us to nail down some long-term target number. We're not going to do that because I think really at the core of this is the question of where there are opportunities which we don't have full visibility to beyond 2020.

Let me just tell you how we think about this. We see a period ahead of prolonged revenue growth for the company because we have a relatively new lineup of products that should continue to grow. We're adding to that even this year and next with additional launches. We do see ourselves balancing R&D spending, both on the balance sheet, M&A, as well as partnerships, and continue to spend, I would say, toward the top of the industry on internal income statement-based R&D because we see good opportunities today. But that is not a fixed line item. It's based on what we see in front of us and the opportunity to create value for shareholders and patients with innovation.

I would expect long term to continue to see as we grow top line better gross margins and better SG&A as a percent of sales, so those will be helpful long term to that continuing expansion. R&D will be more a function of our choice-making on growth drivers for the future, and it's hard to speculate on which direction that would go. We would hope actually to be able to spend more because that would mean the science is promising and we see opportunities to grow the value of the company and improve therapies for patients.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. John, next caller, please.

Operator

We'll go to Geoff Meacham with Barclays. Please go ahead.

Q - Geoffrey Meacham {BIO 21252662 <GO>}

Good morning, guys. Thanks for the question. I just had a few. Enrique, you saw some good sequential trends for Jardiance in 3Q as well as 4Q. So my question is what do you attribute that to, and should the demand backdrop continue into 2019? I know most investors were initially expecting more of an inflection after EMPA-REG; it hasn't happened yet. But are you seeing signs of that happening now?

And then just bigger picture for Josh on the back of the Loxo deal, obviously, you guys have broadened – even more broadened your oncology presence. So from maybe a capacity or from a priority standpoint, where do you see BD fitting in? Is there a therapeutic category that you feel like you maybe need a little bit more help in? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks. Enrique?

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

As we look at 2019, I'm particularly bullish when it comes to Jardiance because we have a number of inflection points that I think are playing as strong tailwinds for the success of the product. As you know, we have new updated ADA and EASD guidelines, I think, that place emphasis on SGLT2s, but in particular preference for Jardiance within that class.

Clearly, we have the re-inclusion of Jardiance in the CVS formularies, and that's pretty significant. And now Jardiance has basically 90%-plus access across commercial and Part D. It is likely that we're seeing as we look at some of the data, when we look at January – when we look at market data, it is likely that we're seeing some spillover effect of that re-inclusion even beyond some of the formulary itself. Jardiance now, it's basically running about in the low to mid-60s when it comes to NBRx share. And we're actually seeing the SGLT2 class accelerate and now basically showing growth in double digits. All of that I think is very encouraging.

And finally, given the profile that we basically have, the increased investment in terms of our competitors, we see that also as beneficial to the product. So, very bullish in terms of how I see this overall class accelerating, and more importantly, Jardiance basically capitalizing as the share leader.

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

Hi, Geoff. Thanks for the question. I think as it relates to business development capacity and interest, first I'd go back to Dave's earlier comments about how we think about the future. We see a period of good growth in front of us, and that good sales growth and operating income growth translates to strong cash flow generation. So I think in terms of capacity, we feel like we've got very good capacity going forward.

So really from a business development perspective, we're going to be mostly constrained by the opportunities that we see. We're not particularly tilted towards one therapeutic area. It's really the therapeutic areas that we're invested in today. When we see good assets where we like the science, can enhance the portfolio and can create value for shareholders with the acquisition, we'll pursue those and we'll pursue them aggressively.

I think just given where investment and the progression of opportunities and science is, you'd have to expect that we will continue to be looking at oncology and immunology are two areas where there's just a lot of opportunity. But all of our therapeutic areas are open for us. And when we can find the best assets, really we've got the balance sheet and cash flow capacity to act.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. John, next caller, please.

Operator

That will be David Risinger with Morgan Stanley. Please go ahead.

Q - David R. Risinger {BIO 1504228 <GO>}

Yes, thanks very much. First, could you please discuss the forthcoming LOXO-292 readouts to watch? And if possible, it would be helpful if you could characterize what percentage of patients could be candidates in each tumor type.

Second, with respect to Novo's oral semaglutide, I think the expectation is that it will be priced lower as an oral. Could you discuss potential implications for the GLP-1 market, including Trulicity?

And then I just have one little nit question, which is for Trajenta, the CAROLINA study versus sulfonylurea completed six months ago in August. When should we expect the top line? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Okay, thank you. We'll go to Anne for Loxo, and then Enrique will take the final two questions.

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

So for LOXO-292, you can expect to see an additional readout at a scientific meeting in the second half of 2019, so we'll be looking forward to that.

The LIBRETTO study is enrolling very well. It has over 300 patients in it now. And so there will be robust data reported at the end of this year. Importantly, as we saw some of the data that was reported last year at some of the various meetings, such as World Onc (49:48), we saw response rates between 60% and 80% depending on the tumor type, and then seeing patients stay on therapy, 90% or higher staying on that therapy. So we remain very excited and encouraged by the LOXO-292 data. We think it's transformative for patients with RET fusions or mutations. And so you'll continue to hear more from that.

On the actual incidence rates, what we know as far as conversations with thought leaders and also reviewing the literature is that with RET fusions in lung cancer, it happens in about 2% to 3% of lung cancers. And so as you know, that's a substantial market, and so that's one of the largest growth opportunities. That could be over 3,000 patients in the U.S. In papillary RET fusions, it's about 10% to 20%, a smaller population, but again, a very strong response rate in those patients.

And then in a tumor such as medullary thyroid, which has activating RET point mutations, that actually happens to about 60% of those patients that they see that RET mutation. And so again, that could be an additional 500 patients in the U.S. alone, and then you start to include the global numbers.

So while the numbers – the incidence rates are not high, the response rates are really remarkable, and so we do believe that we'll see strong penetration and also a long durability of response. So again, very excited about looking forward to those readouts.

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

Very good. David, thank you for the question on oral sema. That is a question for Novo Nordisk. Unfortunately, I'm unable to really speculate on how they're going to price their product and some of the implications.

As far as Trajenta and CAROLINA, we expect to release the top results this quarter – the top line results.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you, Enrique. Next caller, please.

Operator

We'll go to Vamil Divan with Credit Suisse. Please go ahead.

Q - Vamil K. Divan {BIO 15748296 <GO>}

Hi. Great. Thanks for taking my question. So first on Olumiant, just following up on some of the earlier questions, I know the 4-milligram dose may be coming but at least for now with the 2-milligram dose in the U.S., how should we think about the uptake potential, I guess say, for this year, maybe early next year? There's pretty limited sales in the fourth quarter at least. So just trying to get a sense of U.S. versus ex-U.S. dynamics there.

And then for Emgality, I appreciate some of the comments you made there around the dynamics. But just curious how you're seeing the discounting or, say, the net pricing evolve for that market with three players in the space. It looks like you guys have done pretty well in terms of gaining access based on the announcements we've seen, but any longer-term insights would be helpful.

A - Christi Shaw {BIO 19739271 <GO>}

Sure. Thanks, Vamil, for the questions. So I guess I'll take both of those. I'm sorry, Kevin, I kind of just slipped in there in front of you. So on Olumiant, what we see across the globe is really strong uptake, especially with our clinical experience that the patients are having, fast pain relief. And what we see with the 2-milligram versus the 4-milligram is very similar from an efficacy standpoint. The ACR20, it's about 1% less on the 2-milligram versus the 4-milligram. And ACR70, it's about 4% less.

So in the U.S., those physicians who have tried it and the patients' feedback have been extremely positive. Obviously, in the U.S., our indication places us post-TNF. At a 60% discount to the market leader, our access hasn't been an issue. And we think this will be a continued growth product in that small market that we're playing in right now.

We obviously continue to look at the 4-milligram across multiple indications, as I talked about earlier, with atopic dermatitis, lupus. Obviously, the discussion is ongoing in rheumatoid arthritis, et cetera. So we're still very confident in that dose and the benefit/risk profile of that.

As I move on to Emgality then, thanks for asking about the discounting and the net pricing because I forgot to mention. We are very excited to know that starting February 1, we will have best-in-class access in 2019 versus the other CGRPs. We are on all three major PBMs. There has been only one regional player, small regional player that has not put us – that has disadvantaged us to get a CGRP. So we have wide-open access and, relative to our competitors, better access.

I can't really comment on the discounting piece. I can tell you now what we're seeing as the market plays out is the sampling happens in the physician's office. We started right away in the physician office sampling and in retail. So what you see in our NBRx rates is actually no samples in there. It's pure play, only the co-pay piece of it.

And what you see with the market dynamics as well, I've gotten a lot of questions on this. The market flat, we think the market continues to grow, huge opportunity, up to 6 million patients. And with the market dynamics of our competitors changing from specialty, mail order, into retail has made that market chart look a little bit flat versus what we actually think the underlying demand is.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Christi. Next caller, please.

Operator

We'll go to Andrew Baum with Citi. Please go ahead.

Q - Vineet P. Agrawal {BIO 16441538 <GO>}

This is Vineet Agrawal for Andrew Baum. I have two questions please. The first one is, while the HHS net pricing proposal might reduce near-term political pressure and grow price affordability, how concerned are you that it will ultimately spill into the much more profitable commercial plans with material negative pricing implications for you?

Secondly, do you think the second NDC brand strategy for Medicare formularies is commercially viable, or does it materially increase risk of fraud at independent pharmacies? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

So we'll go to Dave for the initial question on the pricing pressure and what we're seeing in the government and any potential spillover to managed care, and then we might need to come back for clarification on the second question.

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

I'm not sure I got all the detail of your question. But I guess I will just caveat this answer by saying it's difficult to speculate right now. Of course, it seems like nearly every week we see some new proposed regulatory rule or introduction of some idea on the Hill as it relates to U.S. drug pricing.

I'll give you our long-term outlook, which is as an innovative-based company, we're of course very excited about the underlying science in this industry and what it can do. The products we've been speaking about today are good examples of that. And I think an innovation-based strategy is the way to overcome whatever the pricing pressures are out there. So we like where we sit. We're in a period of strong growth and we've got innovation flowing now as well as recently launched that gives us a strong base going forward.

We'll adapt to whatever rules come out and how they get finalized. No doubt, I would say it's fair to say the administration is focused on both government formularies as well as spillover into commercial markets. We think that's fine. It's probably difficult to run two systems side by side. And their top priority is actually our top priority, which is lowering out-of-pocket cost for patients at the pharmacy counter so things like and the new rebate rule, this ability to pass through savings and the chargeback form or some other form even as early as this year into Part D plan participants, that's a great idea. And I think that's highly consistent with the policy positions we've taken before.

We'll have to see how the dynamics evolve, but Lilly has got a very strong capacity and capability in managed markets and in working with payer customers. That will serve us well as we navigate this period of change. And I'm confident based on innovation we'll emerge successful.

A - Kevin Hern {BIO 20557573 <GO>}

Could you please repeat the second question so we can try to answer that for you? We didn't pick it up earlier.

Q - Vineet P. Agrawal {BIO 16441538 <GO>}

So do you think the second NDC brand strategy for the Medicare formularies is commercially viable, or does it materially increase the risk of fraud at independent pharmacies in the sense that the pharmacies dispense lower-priced drugs but bill for higher-priced drugs?

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

Maybe I'll try to provide an answer to that question. This is Enrique. We do review all options available to us, including potentially having a second brand. There are a number of reasons where a second brand could be viable. It really depends on the specific situation for the products. So that's something that we always study it very carefully, but I'm not prepared to comment on that at this time.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. Next caller, please?

Operator

We'll go to Umer Raffat with Evercore ISI. Please go ahead.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Sorry. Thanks so much for taking my questions. First, I noticed in some of the deal documents that came out on the Loxo deal, there was a sales estimate from Loxo management of sub-$40 million for 2020. Can you comment on that? And maybe just give us a little more specific metrics on what extent of testing is already happening and how you see that changing, let's say, by year-end 2019? Thank you very much.

A - Kevin Hern {BIO 20557573 <GO>}

Okay, thanks. We'll have Anne take those questions.

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

On the going-forward sales forecast, we don't comment on those specifically, and so I won't comment on that – the details of forecasted sales. This is obviously the launch year for Vitrakvi, and so I think it's too soon to comment. I believe there I would say that things are off to a good start. But again, we'll have to see the full-year performance before we could comment on future performance.

As far as the testing, so importantly, what we're seeing in both TRAK (59:44) and then in RET is obviously in lung cancer we're seeing uptake of testing go rapidly. Our belief is that when we have good medicines, testing tends to follow pretty rapidly. And so it's important for us to accelerate bringing these medicines forward and then driving that testing quickly. Key though you're noting is success in these spaces is getting testing to be

widespread. So our focus is not just on launching these drugs but also partnering with pathologists and diagnostic laboratories and making sure that this testing is routine and available.

We are seeing early adoption at the academic central cancer centers, and so we expect that as those will scale, getting particularly NGS testing to be more routine. And again, we're seeing an increase in thyroid. While it's fairly routine in lung, again with the knowledge out there that there are opportunities in thyroid, we're seeing that testing go forward. And I do believe that advances in testing will also bring the cost down. That's also what we see as key.

So in our launch strategy, it's very much about the partnership with the laboratories, the pathologists to make sure that they understand the value of testing. And I know that Bayer and Loxo agree with this as well.

So we believe that good medicines will drive change in practice, and so we definitely are bringing forward good medicines, and we look forward to helping change the face of medicine, particularly in precision medicine, which is a very high value driver with the fact that with these very strong response rates, the efficiency of the healthcare system is significant. Small numbers of patients, high response rates is a very efficient use of healthcare dollars. So we believe we can change that dynamic pretty rapidly.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you, Anne. Next caller, please.

Operator

And we will go to Steve Scala with Cowen. Please go ahead.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. Christi, may I clarify your comment on the baricitinib atopic dermatitis data? There is only one primary endpoint in the trial. That's investigator global assessment. Is that the one that the 2-milligram missed?

Secondly, MONARCH HER and MONARCH PLUS are not listed in the key 2019 events, but both were expected. Can you clarify?

And then lastly for Enrique, I hate to split hairs, but on the Q3 call you referred to REWIND as paradigm-changing on several occasions. You did not say that today. What has changed in the last three months? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Steve. We'll go to Christi for the first one on bari, then Anne for the MONARCH readout, and then Enrique finally to close out on REWIND. Christi?

A - Christi Shaw {BIO 19739271 <GO>}

So we had a primary endpoint and then we had multiple secondary endpoints, and we're going to be sharing that data at a future scientific meeting, especially as we gain more knowledge with the next three studies that will read out this year.

There were multiple endpoints. Global assessment is a primary endpoint, but then we have multiple secondary endpoints to that, actually eight of them. And so as we know, the 4-milligram met all of the primary endpoints, as I said. The 2-milligram missed on some of the secondary endpoints. So I appreciate you allowing me to clarify that answer.

A - Kevin Hern {BIO 20557573 <GO>}

Anne?

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

Yes, on the MONARCH HER study, we do expect the readout to be in the first half of this year. It is a Phase 2 study, so that's something that we wouldn't note necessarily on those listings. But we do look forward to that readout and then look forward to the next stages of that, so whether we move forward to a Phase 3 study depending on the robustness of the data. So you'll see that read out in the first half of this year.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. Enrique?

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

My enthusiasm for REWIND and Trulicity has not changed at all. If anything, we're even more bullish today than we were maybe a couple months back.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you, next caller, please.

Operator

And, sir, there are no further questions in queue.

A - Kevin Hern {BIO 20557573 <GO>}

Okay, great. Thank you. We'll go to Dave for the close.

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

Great. Thank you, Kevin, and we appreciate your participation in today's earnings call and your interest in the company. We demonstrated again in 2018 clear progress toward our revenue and profitability goals for 2020. The company is executing well. We continue to advance our innovation-based strategy through progressing internally discovered medicines, augmented with business development transactions, highlighted by our

recently announced acquisition of Loxo Oncology. With a robust pipeline and volume-driven revenue growth, Lilly continues to be a compelling investment as we move into 2019.

Thanks again for dialing in today. Please follow up with our Investor Relations team if you have any additional questions we didn't address on the call, and I hope you have a great day. Thank you.

Operator

Ladies and gentlemen, that does conclude your conference. Thank you for your participation. You may now disconnect.