Q4 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
- Joshua L. Smiley, Senior Vice President and Chief Financial Officer
- Kevin Hern, Vice President of Investor Relations
- Mike Mason, Senior Vice President and President, Lilly Diabetes
- Patrik Jonsson, Senior Vice President and President, Lilly Bio-Medicines

Other Participants

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

Presentation

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Lilly Q4 2019 Earnings Call. At this time, all participants are in a listen-only mode. Later, we'll be [ph] conducting a question-and-answer session. (Operator Instructions) As a reminder, today's call is being recorded.

Now I'd like to turn the conference over to your host Kevin Hern. Please go ahead.

Kevin Hern {BIO 20557573 <GO>}

Good morning. Thank you for joining us for Eli Lilly and Company's Q4 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, Chief Financial Officer; Dr. Dan Skovronsky,

Chief Scientific Officer; Anne White, President of Lilly Oncology; Patrik Jonsson, President of Lilly Bio-Medicines; and Mike Mason, President of Lilly Diabetes. We are also joined by Kim Macko and Mike Czapar of the Investor Relations team.

During this conference call, we anticipate making projections and forward-looking statements based on our current expectations. Our actual results could differ materially due to a number of factors, including those listed on Slide 3 and those outlined in our latest Forms 10-K, 10-Q and any 8-Ks filed with the Securities and Exchange Commission. The information we provide about our products 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 1st, 2018.

Now, I'll turn the call over to Dave for a summary of our Q4 results.

David A. Ricks {BIO 16504838 <GO>}

Thanks, Kevin. 2019 was a solid year for Lilly, and our strong Q4 financial results highlight the strength of the underlying business. We exited 2019 with momentum and we'll continue to focus on executing our strategy in 2020, which is to deliver excellent business results develop and launch new medicines for patients and drive increased productivity.

Revenue growth accelerated in Q4, increasing 8% versus Q4 2018, or 9% in constant currency. This strong performance was driven entirely by volume, which contributed 10 percentage points of growth, despite continued headwinds from the loss of exclusivity in the US of Cialis and the global withdrawal of Lartruvo. Excluding Cialis and Lartruvo, worldwide volume growth was an impressive 15%.

Newer medicines continue to be our growth engine, representing 46% of our revenue this quarter. We made good progress in Q4 on our productivity agenda, as operating income grew 10% versus last year. We posted strong revenue growth and held marketing, selling and administrative expenses flat versus last year, while increasing our investment in R&D. Our non-GAAP operating margin was 26.3%, an improvement of 40 basis points versus Q4 2018.

We finished 2019 with a full-year operating margin slightly below our guidance of approximately 28%. As we made targeted strategic investments in Q4 across both our commercial portfolio and pipeline, which will enhance our opportunities for future growth. These investments provide good momentum heading into 2020, and keep us on track to achieve our 31% operating margin target this year.

We've announced multiple pipeline milestones, since our Q3 earnings call. These include positive results in the remaining two Phase 3 trials of the baricitinib BREEZE-AD program

in atopic dermatitis. The submission of selpercatinib in the US and Europe and the FDA granting selpercatinib, a prior to review. The submission of tanezumab for OA Pain in the US in collaboration with Pfizer. The submission of higher doses of Trulicity in the US and Europe. And the submission of baricitinib for atopic dermatitis in Europe and Japan.

During Q4, we put our strong operating cash flow to work, returning approximately $900 million to shareholders via share repurchase and dividend, in addition, as previously announced, we increased our dividend 15% for 2020. This marks the second consecutive year of a 15% dividend increase, reflecting our confidence in the outlook for the business. Finally, we recently announced the pending acquisition of Dermira, the company focused on developing new therapies for chronic skin conditions. Dermira is an exciting -- and has an exciting asset in Phase 3 for atopic dermatitis, lebrikizumab, in addition to a currently marketed product for excessive underarm sweating QBREXZA. This transaction enhances our Phase 3 pipeline and complements our existing efforts in atopic dermatitis with baricitinib. We look forward to closing that transaction here in Q1.

Moving to Slide 5, you'll see the list of key events, since our last earnings call. In our continued efforts to help make medicines more affordable and reduce out-of-pocket costs for patients, we recently announced plans to introduce two additional lower priced insolence. Humalog 75/25 KwikPen and Humalog Junior KwikPen, both products will be available by mid-April, and will be offered at a 50% lower list price compared to the branded versions. Once these additional options are available more than 90% of Lilly's Humalog options will be accessible to help patients reduce their out-of-pocket costs. And we hope to see payers provide increased access to patients for these solutions.

During the month of December alone, Insulin Lispro help nearly 79,000 patients in the US. These recent additions complement existing offerings in the Lilly Diabetes Solution Center, which includes, which currently helps, as many as 20,000 patients per month better afford their insulin. As a company that has been in business for over 140 years and invest over $5 billion per year at long-term research and development, we take our responsibility to pursue sustainable business, social and environmental practices, very seriously.

Now I'll turn the call over to Josh to review our Q4 results and to provide an update on our 2020 financial results.

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.

So looking at the non-GAAP measures on Slide 8, you will see revenue increased 8% or 9% in constant currency. Gross margin as a percent of revenue declined 70 basis points to 79.9%. Excluding the impact of FX on international inventory sold, gross margin as a percent of revenue was 79.6%. And on the same basis, our gross margin percent decreased by approximately 50 basis points compared to Q4 2018, driven by unfavorable product mix in the negative impact of price on revenue.

Moving down the P&L, operating expenses grew 6% versus last year's quarter. Marketing, selling and administrative expenses were flat as cost containment and productivity measures offset investments in key growth products. R&D expenses increased 14% reflecting higher development expenses for late-stage assets, including tirzepatide, selpercatinib and mirikizumab. Operating income increased 10% compared to Q4, 2018, as sales growth outpaced expense growth, resulting in operating income as the percent of revenue of 26.3% for the quarter and 27.2% for the full year. This quarter's results are indicative of the potential for growth and margin expansion our portfolio of new medicines offers. We are well positioned to drive top-tier revenue growth and invest in the next wave of new medicines, while driving margin expansion at the same time.

We exit 2019 with significant momentum executing our strategy and are on track to achieve our 2020 full-year operating margin target of 31%. Other income and expense was income of $206 million this quarter compared to income of $31 million in Q4 2018, driven by investment gains on public equities. As we highlighted previously, this line item can be volatile and public market valuations fluctuate. Gains in Q4 were primarily generated by our investments in China biotech companies through our Lilly Asia Ventures arm and strategic investments in companies focused in newer technologies like RNAi.

While we appreciate the gains, we are even more pleased with the relationships and the potential to develop new medicines for patients that accompany some of these investments. Our tax rate was 12.6%, a decrease of 300 basis points compared with the same quarter last year, driven primarily by an increase in net discrete tax benefits, including tax benefits from the resolution of US and foreign audits. At the bottom line, net income increased 26%, while earnings per share increased 31%, due to a reduction in shares outstanding from share repurchases.

Slide 9 outlines the same non-GAAP measures for the full year. While we are excited with our performance in Q4 and the momentum headed into 2020, we're also pleased with our overall performance for the full year in 2019. Last year, we experienced the full effect of the Cialis patent expiration and the impact of the withdrawal of Lartruvo. In spite of these headwinds, we grew the top line at 5% in constant currency and generated EPS growth of 11%, while investing behind our newer products and pipeline. We also generated good shareholder value and established a strong strategic foundation through our split off of Elanco and the acquisition of Loxo Oncology. As we highlighted in December last year, we are well positioned in 2020 to deliver our five-year financial goals and continue this period of sustained growth.

Moving to Slide 10, we find a reconciliation between reported and non-GAAP EPS. Additional details are provided on Slides 26 and 27.

On Slide 11, we quantify the effect of price, rate and volume on revenue growth. As mentioned earlier, worldwide revenue grew 9% in constant currency during Q4, driven by strong volume growth in 10%, partially offset by price. Foreign exchange had a modest negative impact on revenue growth. For the fourth straight year, we delivered worldwide revenue growth each quarter, despite headwinds from patent expirations.

US revenue grew 7% compared with the fourth quarter of 2018. Volume growth of 8% was led by Trulicity, Taltz, Verzenio, Jardiance and Emgality. Excluding Cialis and Lartruvo volume grew over 50. Pricing was a 1% drag on US revenue growth this quarter impacted by increased funding during the coverage gap in Medicare, unfavorable changes and estimates for rebates and discounts and disproportionate volume growth in lower net price segments, which was partially offset by the net of modest list price increases in higher rebates as well as reduced reliance on patient assistance programs, primarily due to improved commercial access for Emgality. The full year impact of price was a headwind of 3% consistent with our 2019 and 2020 expectations for US price having a moderate drag on revenue growth.

Moving to Europe. Revenue grew 12% in constant currency, driven by impressive 15% volume growth, partially offset by the negative effect of foreign exchange and price. Volume growth was led by Trulicity, Olumiant, Taltz and Verzenio. We're pleased with the uptake of our newer products across Europe and are looking forward to continued strong growth in 2020. In Japan, revenue grew 7% in constant currency driven entirely by volume growth, somewhat offset by a modest pricing headwind due to the government-mandated price decreases that went into effect in 2019. Verzenio, Cymbalta, Trulicity and Olumiant were the key contributors to growth.

Revenue in the Rest of the World increased 14% in constant currency, led by 44% growth in China on the same basis. China growth was driven by strong performance across a number of key products, including Tyvyt, so we're excited about the recent launches of Trulicity, Taltz and Olumiant. The same information for our full-year revenues at the bottom of this slide.

As shown on Slide 12, our key growth products continue to drive impressive worldwide volume growth. These new medicines delivered nearly 15 percentage points of growth this quarter continuing the strong trajectory we've seen throughout 2019. Brands that have experienced loss of exclusivity provided a drag of over 400 basis points driven primarily by Cialis. As a reminder, generic tadalafil entered the US market in September 2018, significantly impacting Cialis revenue with erosion further accelerating in Q2 2019 at multisourced generic tadalafil market. While the impact of this event is beginning to sunset, it still had a meaningful negative impact on growth in Q4 2019.

Slide 13, highlights the contributions of our key growth products. In total, these brands generated over $2.8 billion in revenue this quarter, making up 46% of revenue. Our newest medicines again had impressive results in large and growing therapeutic areas and our ability to reach more patients continues to demonstrate the strength of our commercial execution. Within diabetes, the injectable GLP-1 class continues to add new patients, despite the entry of a new oral therapy.

In the US, total injectable prescriptions grew 29% versus Q4 2018 and Trulicity grew faster than the market, posting an increase of 32% in total prescriptions during the same period. Net pricing in the US for Trulicity declined in the mid-single digits in line with our expectations for Q4 and for 2020. As we discussed on the Q3 call, Trulicity price in Q1 through Q3 of 2019 was impacted by a number of factors that we don't expect to persist in 2020.

SGLT2 Inhibitors accelerated their trajectory as total US prescriptions for the class grew nearly 20% versus last year's quarter and new therapy starts grew over 46%. As the market leader, Jardiance continues to drive strong class growth accounts for over 55% of total prescriptions. Our sustained market leadership in these two important and growing classes within diabetes is a competitive advantage for our diabetes business and positions us well for future growth.

In immunology, Taltz continues to have strong growth, as US total prescriptions grew nearly 40% versus Q4 of 2018. Despite an increasingly competitive market, Taltz gained over 3 share points in dermatology during 2019 and rheumatology weekly prescriptions have more than doubled during that same time frame. In 2020, we look to build on the strong momentum demonstrated in 2019 and reach even more patients. In pain, Emgality continued its US leadership in share of market for new to brand prescriptions at over 47%. While pleased with the uptake, we believe there is room for significant additional growth as we expand our commercial presence in primary care. We continue to see progress with roughly 80% of prescriptions reimbursed at the end of Q4, reflecting the strong access of Emgality.

Within oncology, Verzenio US total prescriptions grew over 46% versus Q4 2018 and the CDK4/6 market is showing encouraging growth as total prescriptions increased by over 16% during the same time frame. Additionally Cyramza continues to post solid growth as we realized thoracic synergies across our portfolio. In addition to the strong performance of our key growth drivers, we look forward to potentially launching three new medicines in 2020, with REYVOW, selpercatinib and Ultra Rapid Lispro. We believe all three new medicines have potential to be first-in-class or best in class and to improve the lives of patients. In addition, launching new medicines in the therapeutic areas where we have existing commercial infrastructure will support further margin expansion.

Slide 14, shows the year-over-year change in select lines of our income statement focusing on our non-GAAP results, foreign exchange rates had a negative impact on revenue, gross margin, operating income and EPS and a modest net positive impact on operating expenses.

On Slide 15, we provide an update on capital allocation. In 2019, we invested over $13 billion to drive our future growth through a combination of business development, capital expenditures and after-tax investment in R&D. In addition, we returned approximately $7 billion to shareholders via dividends and share repurchases. As Dave mentioned earlier, we also announced a 15% dividend increase for the second consecutive year showing our confidence in the outlook for the company. We are focused on utilizing the strong cash flow our business generates to develop the next wave of new medicines through both internal and external sources, as highlighted by the recently announced acquisition of Dermira. We remain active in assessing bolt-on acquisitions or in-licensing where we can create shareholder value and enhance our future growth prospects.

Turning to our 2020 financial guidance on Slide 16, you will see that we've updated our non-GAAP guidance to reflect the impact of the planned acquisition of Dermira and our recent strong business performance. Specifically, we are increasing our revenue range by $100 million to include QBREXZA and to reflect strong prescription trends we see in the

underlying business. Updating our SG&A guidance to account for the addition of the Dermira sales force in the commercial expenses to support QBREXZA and maintaining all other line items and confirming our non-GAAP earnings per share range of $6.70 to $6.80 and operating margin target of 31%. On a reported basis, the impact of the Dermira acquisition will have an impact of $0.21 and earnings per share for 2020 is now expected to be in the range of $6.18 to $6.28. We continue to execute our innovation-based strategy, while leveraging our young commercial portfolio of new medicines to drive margin expansion over the mid-term.

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

Daniel M. Skovronsky {BIO 15349505 <GO>}

Thanks, Josh. Slide 17 shows select pipeline opportunities as of January 27. Positive movement, since our last earnings call includes the submission of selpercatinib in the US and Europe as well as the initiation of Phase 3 trials for selpercatinib in patients with RET fusion-positive non-small cell lung cancer or RET-mutant medullary thyroid cancer. The submission of tanezumab in the US for osteoarthritis pain. The submission of higher doses of Trulicity for type 2 diabetes in the US and Europe. The submission of baricitinib for atopic dermatitis in Europe and Japan. The addition of lebrikizumab for atopic dermatitis to the Phase 3 portfolio pending the closure of the Dermira acquisition. The initiation of a Phase 3 study of tirzepatide in obesity and a Phase 2 study of tirzepatide in NASH. The initiation of Phase 2 for our checkpoint agonist CD200R and immunology in the initiation of Phase 1 for four assets, as well as the termination of three early stage oncology assets.

In addition, we had some important early stage readouts, including LOXO-305 or novel BTK inhibitor, which we highlighted on the 2020 financial guidance call and continues to progress quickly in development. We also had internal data readouts from two Phase 2 trials of pegilodecakin in combination with immunotherapy agents in patients with non-small cell lung cancer, Cyprus 1 and Cyprus 2. Although the full data will be presented at a medical meeting later this year, I can say that both studies were negative. Though we are disappointed in the lack of efficacy for pegilodecakin in combination with checkpoint inhibition in lung cancer, we remain committed to finding new therapies for people with cancer. Although, we are still analyzing the totality of the data that we have obtained with pegilodecakin, at present we do not anticipate additional trials with this agent.

Moving to Slide 18. We show a final tally of how we finished 2019 versus the key events we expected to occur. 2019 was a very productive year and we made significant progress in bringing new medicines to patients. In total, we added four new Phase 3 clinical programs to our pipeline all with the potential to be first-in-class or best-in-class. We reported 12 positive Phase 3 or registrational trial readouts, including a mix of NMEs and new indications or new data for launched products. We submitted 12 NMEs or new indications for regulatory review in geographies around the world. And we received positive regulatory action on two new medicines REYVOW and BAQSIMI as well as four important new indications across Trulicity, Tatlz, Emgality and Cyramza. We're proud of the significant achievements we made in 2019. And we're focused on discovering and developing more new medicines to help patients as we enter another promising decade.

Moving to Slide 19, while it's early in the year, we've already made good progress on our 2020 goals having announced the initiation of additional Phase 3 trials for selpercatinib, positive results in the remaining two trials of the baricitinib BREEZE program for atopic dermatitis. The submission of baricitinib for atopic dermatitis in the EU and Japan. The submission of tanezumab for osteoarthritis pain in the US in collaboration with Pfizer. FDA approval of Trijardy a fixed-dose combination of empagliflozin, linagliptin and metformin XR and regulatory approval of Cyramza for first line EGFR positive non-small cell lung cancer in Europe.

Before turning the call back over to Dave, I'd like to spend a few minutes providing additional details on important milestones for two clinical programs that I mentioned earlier, but is the initiation of additional clinical trials for tirzepatide and the completion of the baricitinib BREEZE-AD atopic dermatitis program. Beginning with tirzepatide on Slide 20. We previously shared our plans to initiate a cardiovascular outcome study for tirzepatide this year, assessing tirzepatide head-to-head against the most widely used GLP-1 therapy by Trulicity. This is a bold move. It signals both our confidence and the strength of tirzepatide as well as our desire to deliver meaningful data for patients and physicians on how new medicines measure against the leading therapies. Through very collaborative discussions with the FDA we've gained alignment on the key design features of this unique study called surpass-CVOT. This trial will include approximately 12,500 patients with type 2 diabetes and confirmed atherosclerotic cardiovascular disease and we'll measure time to first occurrence of the composite endpoint of CV death, myocardial infarction or stroke. The study will assess both non-inferiority and superiority of tirzepatide versus Trulicity. And we anticipate it will take just over four years to complete.

In addition to surpass-CVOT, we're pleased to share that the Phase 3 type 2 diabetes program surpass is progressing extremely well. Investigator interest has been very strong in four of the eight surpass clinical trials are already fully enrolled. We look forward to sharing top line results for the first study to readout from the surpass program later this year. Finally, we're excited that the surmount Phase 3 obesity program is actively dosing patients and that the synergy Phase 2 program in NASH is currently underway as well. Given the profound weight loss seen in Phase 2 trials of tirzepatide, we're excited about the potential opportunity these additional clinical programs presents to help patients. Together with the ongoing surpass studies these additional studies will expand the current Phase 3 tirzepatide program to over 20,000 patients. We're excited about the breakthrough that tirzepatide represents for patients and we'll continue to invest fully to maximize this opportunity.

Moving to Slide 21. We recently announced the completion of the final two studies of the BREEZE-AD clinical program; BREEZE-AD4 and BREEZE-AD5. The full BREEZE program was comprised of five studies assessing baricitinib in both monotherapy and in combination with topical corticosteroids in patients with moderate to severe atopic dermatitis. While not all the data have yet been presented, we're particularly encouraged by the strong results for the 2 milligram dose in the US trial. We believe that the full data package generated from BREEZE-AD shows the potential that baricitinib could offer as an additional treatment option for patients with atopic dermatitis, where there are limited choices. In addition, these data add to the large safety database of baricitinib having over 10,000 patient years of safety data. We recently submitted baricitinib for atopic dermatitis in the EU in Japan and we expect regulatory action late in 2020. We plan to submit in the

US later this year. We anticipate that baricitinib will be the first oral JAK inhibitor for the treatment atopic dermatitis and we look forward to bringing in new treatment option to patients.

Finally, we recently announced the planned acquisition of Dermira. Pending deal closing this transaction would add an additional medicine to the Lilly pipeline for moderate to severe atopic dermatitis, that is lebrikizumab, which is an injectable antibody targeting IL-13 currently in Phase 3 trials. We view lebrikizumab is highly complementary to our efforts with baricitinib in atopic dermatitis. The unmet medical need here is large and we anticipate physicians and patients. We use a range of oral and injectable therapies similar to current common practice for the treatment of psoriasis.

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

David A. Ricks {BIO 16504838 <GO>}

Thank you, Dan. Before we go to Q&A, let me briefly sum up the progress we've made in the fourth quarter of 2019 and the full year. We delivered impressive performance in Q4. Our revenue grew 8% as our newest medicines were again the catalyst for volume basis growth. Our worldwide prescription trends are strong and we are well positioned entering 2020 to continue our positive trajectory and deliver our 2020 financial guidance.

We advanced our productivity agenda controlling operating expenses while investing behind key commercial growth drivers and our late-stage pipeline. We grew sales in Q4, while keeping marketing, selling and administrative expenses flat versus Q4 2018, demonstrating our ability to drive margin expansion. We made important pipeline progress in Q4, capping a year that featured significant new additions to the Phase 3 portfolio several positive readouts in Phase 3 trials and a multitude of regulatory submissions and approvals. Finally, we returned nearly $600 million to shareholders via the dividend and completed $300 million of share repurchases as well.

As we shared during our 2020 Financial Guidance Call last December, we are in the early stages of a period of sustained growth at Lilly. The balance of new medicines we plan to launch over the next five years and the continued scaling of our newer medicines compared to our limited patent exposure sets up an exciting period ahead. We are pursuing new medicines and some of the most important diseases with both significant unmet medical need and sizable business opportunities. We are pleased with our finish to 2019 and our position of strength as we enter 2020 and the next decade of this company's history.

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

Kevin Hern {BIO 20557573 <GO>}

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

Questions And Answers

Operator

Thank you. (Operator Instructions) Our first question is going to come from the line of Geoff Meacham from Bank of America Merrill Lynch. Please go ahead.

Q - Geoff Meacham {BIO 21252662 <GO>}

Good morning, guys. Thanks for the question. Just had one on Taltz and one on the Olumiant filing in AD. So for Taltz, the growth has been solid, but what would you say, it could be a demand tipping point looking to 2020 and beyond is a new contracting agreements as it a broader indication base. Do you have to invest more commercially. And then on the Olumiant filing in AD, I wasn't sure the effect of the 4-mg dose changes the regulatory conversation in the US that you've had in the RA indication since approval obviously was mostly focused on the 2-mg indication, or the 2-mg approval, but wasn't sure if that changes at all on the back of this new data. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Geoff. We'll go to Patrik for both of those questions.

A - Patrik Jonsson {BIO 21139959 <GO>}

Well, thank you very much. We are very pleased with the performance of Taltz in the fourth quarter last year with the growth of total Rx with approximately 40%. If we look at the different spaces, first of all, dermatology, despite the increased competition, we think we are holding ground very nicely, and we are maintaining our total Rx share of market in Q4 despite the increased competition. Also, added to the body of evidence, the head-to-head data versus strength via the IL-23 where we again demonstrated superiority on the skin clearance. And that's the third study combined with Stelara and in Enbrel where we have again demonstrated superiority. So we are confident in continued growth in the space of dermatology.

The biggest opportunity for us remains being in rheumatology where we, in Q4, announced the old IL-17 to demonstrate superiority versus HUMIRA in the SPIRIT head-to-head study. And we saw some significant acceleration in Q4 in terms of new-to-brand, and we are confident that we will continue to grow in the rheumatology space where there are a lot of opportunities for us. We also filed during the second half of the last year the non-radiographic axSpA, and that's an indication where we also see a lot of patients that are not being appropriately diagnosed and even if diagnosed, not appropriately treated. Lastly, both in dermatology and rheumatology, a huge amount of patients are still treated with amputee and F alphas. In dermatology, 40%; and in rheumatology, 70%. And we believe that, that remains the biggest opportunity for all new assets to ensure that patients are being upgraded to new modern more efficacious and safer treatments.

In terms of Olumiant, while we don't comment on regulatory actions for specific brands, we continue to explore options to get the 4-milligram dose get approved in the US However, in the light of most recent regulatory actions with other JAK inhibitors, we're

also realistic in terms of our expectations to get 4-milligram approved in the US in the near term. But as Dave mentioned, we are very much encouraged by the 2-milligram data of Olumiant in atopic dermatitis and where we're demonstrating hitting our primary objective both in terms of at least 75% improvement on skin inflammation, but also in terms of patient-reported outcomes, improvement on itching. So that is encouraging for us in terms of the Olumiant submission in the US.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Patrik. Jeff, thanks for your questions. Next caller, please.

Operator

Thank you. Next question is going to come from the line of Chris Schott from JP Morgan. Please go ahead.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks very much. First question was just on the quarterly progression of sales and earnings as we go through 2020. I think last year we saw a depressed first quarter sales relative to the rest of the year that surprised the street a bit. Should we expect a similar gating of sales in 2020 and are there any particular products we should be watching where I guess 2020 kind of resets the plans could impact those first quarter results.

My second question was just on the Alzheimer's strategy more broadly. How would the approval or I guess not of aducanumab impact how you're thinking about your pending Alzheimer's readouts and development strategies from here. Thanks very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Chris. We'll go to Josh for the first question, and Dan, for the second one.

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

Thanks, Chris. If we look at 2020, we don't provide quarterly guidance. But if we look at sort of the trajectory of sales that we'd expect, if you look at our guidance for the full year, we're in somewhere in the high single digits for sales growth. We'd expect that, that kind of growth to be pretty consistent through the year although keep in mind, in Q1, we still will have a little bit more of the overhang from things like Cialis. So you might expect to see a little bit more sales growth through the year, but pretty consistent. On an absolute basis, though, Chris, we do always see sales in Q1 lower than Q4. A lot of that just has to do with shipping patterns and otherwise. So again, growth should look good in Q1 relative to the year. Absolute sales will be less. I think that's a trend that you see, I'm sure, across almost all companies. There's nothing unique going on there other than normal shipping patterns between Q4 and Q1.

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

Okay. Chris, thanks for your question on Alzheimer's strategy. Of course, we, like many others, will be watching aducanumab closely. And of course, we'll adapt our plans and thinking to meet wherever we see the regulatory bar placed. But I don't think you should

expect us to pivot in our Alzheimer's strategy one way or another. We've placed some pretty important bets. We're excited to see those readouts over time both with solanezumab, but also our own plaque-clearing antibody, donanemab, as well as our tau -- anti-tau antibody that's in Phase 2. We also have a tau small molecule in Phase 1 and other agents earlier in development. So we'll continue to progress those. We think we have smartly designed trials that will give us important readouts over time.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Thank you. Our next question is going to come from Louise Chen from Cantor. Please go ahead.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my questions here. So first question I have for you is, can you provide more color on what might be driving your stronger volume growth when compared to other companies out there in the space, and if this is durable over the longer term? And then my second question for you is, with this growing competition in atopic dermatitis, where do you see Lilly fitting into the evolving treatment paradigm? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you. So we'll go to Josh for the first question and Patrik for the second. Thanks.

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

Thanks, Louise. Good morning. I think in terms of volume growth, what we see at a corporate level is a function of our portfolio. As we mentioned, about a little bit less than half of our sales are coming from new products that we've launched since 2014, 10 of those. They are all still in -- very much in their growth phases: Trulicity growing at 31%, for example; Taltz at 37%. So we've got a relatively young portfolio. We expect the volume gains that we saw in Q4 to be sustainable between 2020 and 2025. As we mentioned on our guidance call, we expect to see top-tier revenue growth over that period. And it will be driven by volume gains. It will be driven by that cohort of products as well as the new launches that we'll expect over this period, including the 3 that we're planning for this year. You couple that going forward with less generic exposure than probably most of the companies that we compete against or that you cover, and I think that would certainly say to us that the volume gains we're seeing are something that we're planning for and think are sustainable.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Patrik?

A - Patrik Jonsson {BIO 21139959 <GO>}

Well, currently, it's estimated that approximately 18 million Americans are suffering from atopic dermatitis, and 10 million of those are suffering from severe to moderate atopic

dermatitis. And the treatment opportunities are very limited. One is saying is that the field of atopic dermatitis is pretty much where psoriasis was 15 years ago. And in the light of that, we believe that we are extremely well positioned. As we shared, we are encouraged with the most recent data on Olumiant both in the US and outside the US And we have submitted Olumiant for approval in Japan and EU, and we take regulatory actions in 2020 here in the US And we believe that Olumiant could definitely be an option for patients that are having fear of injection.

And we are also excited about the announcement we made a few weeks ago about our intent and aim to acquire Dermira. And lebrikizumab is the big driver of that deal. And we see lebrikizumab, based upon the Phase 2b data, as a medicine that will at least be competitive with DUPIXENT and with an opportunity to even be best-in-class differentiating an itch. So overall, we believe that we can play a very important role in the field of atopic dermatitis with both the first oral JAK inhibitor for patients who have fear of injection and a potential best-in-class medicine in lebrikizumab.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Thank you. Our next question will come from the line of Tim Anderson from Wolfe Research. Please go ahead. I apologize. Our next question that will come from the line of Umer Raffat from Evercore ISI. Please go ahead.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my two questions. And both of them are Kevin's favorite topic. So the first one is on CNS penetrants of your GLP-1, and I have two parts on this first one. So there is feedback out there that Trulicity doesn't cross blood brain barrier very much, perhaps in part because of its size, hey, can you comment on that. And in that same question, I also want to ask tirzepatide does not have an IGG. So presumably it should have good CNS penetration. I just want to make sure I hear your take on, on the CNS penetrants of both Trulicity and tirzepatide.

Secondly, Dave, perhaps for you. So the A4 trial and asymptomatic Alzheimer's, my understanding is fully enrolled in December 2017. And at this point, it's already past two years in every single patient. And by end of 2020, you would have hit a three-year landmark in every single patient. So my question is strategically thinking, if regulators are being more accommodating of late, wouldn't it make strategic sense to possibly consider taking an efficacy read at three years, because even at three years, it's 2x the duration of all prior solanezumab trials. Thank you very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Umer for those questions. This is butler bulldogs basketball is probably my favorite topic, but we don't cover that on the call. This is a close second though. We'll go to Dan for both of these.

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

Okay, great. Thanks, Kevin. So with respect to CNS penetration of GLP-1s, you're right that these are large molecularly molecules. Actually, both the Fc-fusion molecules like Trulicity and also, isolated peptides like tirzepatide. Those modifications of the peptides are what gives them the long half-life that enables once-weekly injection. And molecules of that size typically don't penetrate the blood-brain barrier. Having said that, we don't see those attributes, blood-brain barrier penetration, as being important for the efficacy of this class of drugs as evidenced I think by the tremendous efficacy that we've seen with Trulicity and an unprecedented efficacy that we've seen with tirzepatide. So I think that addresses that.

With respect to A4, you're right that this is longer duration trial than, really, I think, any other large Alzheimer's trial has ever been. The reason for that though is because these patients are asymptomatic at the beginning of the trial. So they're very early in the disease course. And it takes a great deal of time to let these patients progress in their disease course. And it's only through progression of patients on the placebo group and hopefully differential less progression of patients on therapy that we could hope to see effective drug. So that's why the design includes such a long follow-up period.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. And Umer, thanks for your questions. And we'll go to the next caller, please.

Operator

Thank you. And once again we're going to have a question from the line of Tim Anderson from Wolfe Research. Please go ahead.

Q - Tim Anderson {BIO 3271630 <GO>}

Oh, hi. A question on your PD-1 with an event and really plans for that product outside the US. It seemed like last summer when I talked to management it was really describe as a China only opportunity with limited potential, but it seems that you may have pivoted in recent months and may have bigger plans to bring them into other geographies. So I'm hoping you can give us your latest thinking. And then second question is just on the DIAN-TU Alzheimer's trial. Confirming that we should see those results really any time. Can you confirm that. And then just how do you view odds of success, it kind of seems to me that it's highly improbable that this will yield positive results for solar, but what are your views. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Tim. We'll go to Anne for the first question and Dan for the second.

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

Well, Tim, thanks for the question on Tyvyt and our business collaboration. So as you said, our current focus is on development and commercialization of Tyvyt in China. However, Innovent's been really important and a terrific strategic partner to us, and so we're always open to discussing opportunities to expand that for mutual benefit. There's really not

more we can say at this time. We're really pleased, I think as Josh and Dave mentioned, with the performance of Tyvyt in China. It's been a remarkable story, and really now, as you know, the only PD-1 that's included on the NRDL list, and I think that demonstrates how the NHSA has recognized its clinical value. And then we were able to share the great news that we have the first-line nonsquamous readout at interim. It's positive. So we'll be planning to submit that this year and that we expect additional readouts in first and second line squamous this year with Innovent. So it's been a great product, and we look forward to what more we can do here, but thanks for the question.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anne. Dan?

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

Yeah, Tim, on DIAN, just a reminder for everyone that this is a dominantly inherited type of Alzheimer's. It's a rare and sort of severe and fast-progressing form of Alzheimer's disease where we're testing solanezumab. Your question on timing of results, we don't have the data yet, but we do expect that this quarter. In terms of the odds to success, I think it's hard to speculate. But as you know, this is a very small trial. A small population is being studied. And it is, as I said, a severe form of Alzheimer's. So those factors weigh against it. There's other factors that weigh for it. We know that it's driven by mutations here in amyloid overproduction and has a relatively longer follow-up. But we'll just have to wait and see data.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Thank you. Our next question is going to come from the line of Andrew Baum from Citi. Please go ahead.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. A couple of questions. Firstly, in relation to the tirzepatide, you highlighted the planned (inaudible). There's been some literature where the patent is that it may not be (inaudible)

A - Kevin Hern {BIO 20557573 <GO>}

Hey, Andrew, this is Kevin. Andrew, we're really having trouble hearing you. Can't really pick up the question other than we heard tirzepatide.

Q - Andrew Baum {BIO 1540495 <GO>}

No. Kevin

A - Kevin Hern {BIO 20557573 <GO>}

Not much.

Q - Andrew Baum {BIO 1540495 <GO>}

Can you hear me?

A - Kevin Hern {BIO 20557573 <GO>}

Yup. We'll try it.

Q - Andrew Baum {BIO 1540495 <GO>}

So my question is on tirzepatide. Talking about Talking about your OUTCOME trial, you're running a head-to-head trial versus Ozempic, which has been described as a high bar. There is some literature on potentially GL -- GIP agonism. If agonism could potentially be increasing cardiovascular rather than decreasing risk, given its evidence as a marker of heightened cardiovascular disease as well as some preclinical data. Perhaps you could talk to your thoughts on the relevance of that literature.

And then second, more broadly, we like to think that Lilly is perhaps a better place than many of your peers in understanding the direction of this particular administration in terms of health care reform. There have been some discussions about whether the IPI proposal could be expanded to include Medicare Part D drugs rather than just the part B. Perhaps you could share your thoughts on what you expect in that direction. Apologies for the line quality.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Andrew. We'll go to Dan for the question on tirzepatide and then Dave on the policy question.

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

Yeah. Thanks. First of all, just a clarification, that tirzepatide trial is head-to-head against Trulicity. Look I think that there is a little bit of literature out there as you referenced about effects of GLP-1, but our thinking is really based on the clinical data that we've already obtained with tirzepatide in the Phase 2 trials. I think everything we see in those trials going into a large cardiovascular benefit for a drug like this. And so that's the driver that's what gives us confidence is the real clinical data with this molecule. The combination of GLP-1 and GLP-1 gives certain effects, which we are able to see. So for example the improved A1C control and notably very dramatic improvement on weight loss, which I think will drive the cardiovascular benefits even higher than we saw in Trulicity.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Dave?

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

Yeah. So on the policy front, we continue to advocate for change in the US system because although we're in a -- as an industry and certainly is moving a deflationary price environment. Those savings are not reaching consumers at the pharmacy counter. And so either through a combination of -- but progress is difficult in congress. So we continue to

advocate for change on behalf of patients though. As it relates to IPI, this proposal was part of the Blueprint and spring of 2018. It's been sitting out there for a while where we have to see any draft guidance for proposed rule making or any version of this in detail. There's always a lot of swirling rumors about it, including expanding it other parts of government programs or changes to it, in terms of the objectives. We see it largely is misguided primarily because in Part-B patients hardly have any cost sharing to begin with.

So, if we're worried about out-of-pocket cost for patients, IPI will do very little it's mostly just a punitive measure against the industry going back to decisions made on European pricing sometimes decades ago. It won't probably change those prices in Europe, if that's the presence goal, and it certainly won't change the affordability equation for patients in the US. So we oppose it for those reasons. That said it's administrative potential action and we'll have to read it if it comes out and decide what to do from there, but it pretty much is a difficult thing to support for our industry and you probably see pharma universally oppose it. So, we'll wait and see.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Our next question will come from line of Seamus Fernandez from Guggenheim. Please go ahead.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Well, thanks for the question. So maybe the first question is really for Josh. Josh, can you just help us understand the progression of margins as we move through the balance of next year -- or sorry, this year in 2020? When I look at the original guidance from this year, I think you guys had said 28% was the target. I think, ultimately, we ended up at 27.2% at the final point of the year. But on the guidance call in December, you had -- you stated and reiterated the 31% target. Can you just help us understand the path to that 31%? Just because the second half of this year I think kind of came in below investors' expectations to some degree and we're just trying to understand a little bit better the very strong move in margins going higher. Obviously, the pieces of guidance makes sense. I think we're just trying to understand the path as we move through the balance of the year. And then the second question, the pegilodecakin update, thanks for that, appreciate the understanding and the challenges. Can -- maybe Jake can just sort of update us on his thoughts. And also, Dan, could update us on your thoughts for the growth of the oncology development portfolio and directionally where you're headed?

A - Kevin Hern {BIO 20557573 <GO>}

Josh, and then Dan.

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

Great. Thanks, Seamus. In terms of margin this year, again, we've reiterated that we're on track for 31%. And the one thing we have said is Q1 will likely be below 31%. That's mostly a function of the less absolute sales that I talked about on a prior question on top of a

relatively fixed OpEx absolute amount. So I think as you look or model OpEx for the year, we see that as pretty constant. On an absolute basis quarter-over-quarter, of course, some small variation. And then you'll see absolute sales dollars on a quarter-over-quarter basis grow. So we don't expect to be at 31% in Q1, but that's -- again, that's a function of the dynamics of the growth through the quarters.

Remember, though, in terms of how to get there in totals for the year, we said for 2019 that we would grow our R&D at an unusual growth rate in 2019 as we scale up programs like tirzepatide and mirikizumab. In 2020, those programs are running at more like full speed. We're able to bring in an asset like Dermira and keep that with a relatively smaller growth rate in R&D. So I think we're confident that the sales growth that we're seeing, that we talked about in Q4 in our -- should persist for the year on top of a slower growing OpEx that we can predict and manage will get us to 31%. And again, I wouldn't be too concerned in Q1 if we're not at that level, but you should expect it as we move through the year.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Dan.

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

Thanks for the question on oncology strategy. Of course, on the last call we talked about our Loxo Oncology at Lilly and how that's changed Oncology strategy. And we're quite pleased with the progress that we've made on executing against that strategy. You can see some portfolio changes in our pipeline update and we also talked about the three key early-stage programs; 305, KRAS and SERD all of which are progressing in the clinic. While we said we're going to focus a lot of our resources on high probability sort of biology that's well understood bets like those, we will also from time to time continue to pursue more novel biology higher risk, high reward bets like pegilodecakin was. And that will be a smaller part of our portfolio in the future.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Our next question comes from the line of David Risinger from Morgan Stanley. Please go ahead.

Q - David Risinger {BIO 1504228 <GO>}

Thanks very much. I have two questions. First, just going back to the high level on GLP-1s in Alzheimer's. Novo has recently convened enthusiasm about the potential for GLP-1 treatment in Alzheimer's. Could you just comment on your view of whether GLP-1 treatment over a few years can actually change the progression of Alzheimer's? And then second with respect to high dose Trulicity, could you please frame what we should focus on when we see the Phase 3 data and your planned positioning of that product? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. We'll go to Dan for the first question. And Mike, for the second one.

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

Thanks. Of course we're aware of the comments that Novo has made on GLP-1s in Alzheimer's disease and the potential there. Look forward to seeing data from that first trial. Look, I think that we know that GLP-1 treatment has beneficial cardiovascular outcomes, including we've seen reductions on stroke. Probably that's the tip of the iceberg, and there's other sort of micro infarcts that are decreased by GLP-1 therapy that could, over time, contribute to a slower rate of kind of decline. Is there a direct effect of GLP-1s on Alzheimer's pathology? I think that's not yet known. So we'll watch how the field evolves. If it turns out that there are great opportunities, I think we have a best-in-class incretin in the form of tirzepatide, and we'd be open to future opportunities with it.

Q - Chris Schott {BIO 6299911 <GO>}

Thanks, Dan. Mike?

A - Mike Mason {BIO 18347681 <GO>}

David, thanks for your question on our favorite subject. Trulicity had another great quarter, growing by 32% on volume and 29% on revenue. We're still quite excited about the overall GLP market growth. The 52-week rate was at 29.7% while the monthly grade in December was at 31.5%. So the market continues to grow. And Trulicity continues to hold up in a very strong market share leadership position outpacing TRS class growth in the face of semaglutide product launches. So we expect that both the new Trulicity REWIND as well as the high-dose label enhancements will continue to drive class growth as well as solidify our market leadership position place. So we're excited about that I think as you take a look at the results there, take a look at increased -- or the A1c results as well as the weight loss results. And what we think is the strength of Trulicity is the fact that you get real-world benefits by having powerful efficacy simply delivered. And this will just give people using Trulicity another reason to stay on it.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Thank you. Our next question will come from the line of Terence Flynn from Goldman Sachs. Please go ahead.

Q - Terence Flynn {BIO 15030404 <GO>}

Great, good morning. Thanks for taking the questions. The first one is on tirzepatide and the CVOT trial. I was wondering if you can share any more details on the stats or powering assumptions there as well as the discontinuation rate that you're assuming in the arms of the trial? And then for Emgality, you mentioned look into the next phase of growth here in the primary care market. What are some of the markers beyond obviously sales that we

should look to in terms of gauging successful uptake there? And then any thoughts on potential impact from oral CGRPs? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Okay, thanks. We'll go to Dan for tirzepatide, and then Mike and then Patrik for the oral CGRP question.

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

Yeah. Thanks for your question asking for more detail on the tirzepatide surpass-CVOT trial design. I think at this moment, we don't sort of comment on any of the finer details around clinical trial design and dropout rates. But I would say that having a trial like this where it's a head-to-head with two great active drugs one on each arm, should be a very compelling opportunity for enrolling positions and a great opportunity for treatment for patients as well. So I think that those kinds of factors should help with both enrollment and retention in the trial.

A - Kevin Hern {BIO 20557573 <GO>}

And Mike?

A - Mike Mason {BIO 18347681 <GO>}

I would agree. I think as we look at the opportunity and really learn from what providers and payers want, they want active comparators. I think this provides a lot of value, a lot of insights into the incremental value of one product over another product. And so obviously, doing a head-to-head trial versus Trulicity is a bold bet, but I think it really reinforces the confidence we have in tirzepatide in this population. So we're very excited about the study. It is a bold bet but one that we're very excited about the potential of this product and CVOT.

Q - Terence Flynn {BIO 15030404 <GO>}

Thanks. Patrik?

A - Patrik Jonsson {BIO 21139959 <GO>}

Thank you. If we look at on the prevention market, we have currently 6 million patients eligible for prevention treatment in the US, but only 3 million of those are being treated. So that's a big opportunity for us with the increased competition in the marketplace as well to drive patient population. And specifically for Emgality, if we look upon the prescriber base today, it's relatively limited. And only 15% of our targets are currently regularly prescribing Emgality. So that's where we see a tremendous opportunity both in specialty care as well as in primary care.

In terms of the oral CGRPs, I think it's important to have in mind that they are only approved or will be approved for the treatment of acute migraine this year, and the prevention indication is coming later on. We are very confident with the profile of Emgality, particularly taking into account that we are now the market leader and the preferred CGRP in the marketplace and particularly with the differentiation we have in the

label with both efficacy at 50%, 75% and 100% level and also the convenience that the device offers from the same device platform as Trulicity.

The oral CGRPs will be competing in acute space, and we are also very excited about the announcement that was the prepublication notice from the DEA that was publicly displayed this morning and will result in an announcement in the federal register tomorrow enable us to bring REYVOW to the marketplace probably late next week. And that's where we have a tremendous opportunity to bring more value in the space of acute migraine. And for the first time, we will be able to talk about complete pain elimination already after two hours with one single dose of REYVOW. And not just complete pain elimination, but also complete elimination of bothersome symptoms such as sun phobia, light sensitivity and nausea. So we believe that we are very well positioned both in the preventive space as well as the acute phase, but patient activation will be key. And that's something that will be beneficial with also new entrants in the marketplace.

A - Kevin Hern {BIO 20557573 <GO>}

Thank you, Patrik. Terence. Thanks for your questions. Next caller, please.

Operator

Our next question will come from line of Steve Scala from Cowen. Please go ahead.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. I have a couple of questions. I'll take the other side of an earlier question and suggest it would be surprising if DIAN-TU didn't hit its endpoint, given the signal you saw in the expedition trials and the fact that DIAN-TU is testing a higher dose in a more homogeneous population for a longer time with the tailor-made endpoint. So Dan, I'm trying to understand your pessimism. And maybe you could please tell us on which of the points that I stated you disagree? And then there are four components to the primary endpoint. Do you need to hit all four to achieve success? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Steve. Dan?

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

Okay, Steve. So look, I think most of the comments you said are right, the importance of those factors in the outcome of the study is what we don't know. And there are other factors. As I said earlier going against us here. The one that gives -- should give anyone the most pause I think is the small sample size and Alzheimer's trials are I think even in large trials notorious for surprising us because of the heterogeneity of that fact and variability in the outcome measures. So it's factors like that, that could make it difficult to really know what is true. Look, I still think it's regardless an interesting scientific question. Important experiment will look forward to seeing the data. With respect to the specifics around the composite, I think the nature of a composite is that you have to hit the overall composite score as the primary endpoint, which could be driven by the various sub-measures or not, but as you point out, this was custom-made for this trial.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

We have a question from the line of Navin Jacob from UBS. Please go ahead.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi. Yes, thanks for taking my questions. Just on Verzenio, Pfizer has slightly delayed its IBRANCE adjuvant trial PALLAS to early 2021. Wondering, and they highlight the event rate progressing much slower? Wondering, how relative to your expectations the event rate has been progressing in monarchE and is the timeline still for an early 2021 read out? And any color on the potential for an interim would be appreciated. That's on Verzenio.

And then just on Humalog, the prior year, I think the press release suggested that pricing in the US benefited from a better segment mix. Is that because of the volume shift to the Humalog authorized generic and that's assuming that the authorized generic is being recorded within the Humalog revenue line I just wanted any -- if you could provide any clarity on that. Thank you so much so much.

A - Kevin Hern {BIO 20557573 <GO>}

Great, thank you. We'll go to Anne for the question on Verzenio and Mike for the question on Humalog.

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

Navin, thanks for the question on Verzenio. So as you know we have not disclosed any interim analysis. Now this is an event driven trial similar to PALLAS. But our estimates make us quite confident that we're looking at a read out in the first half of 2021. So we continue to expect that. And as you know, the trial enrolled remarkably well. And so we able to roll ahead of schedule, which helps obviously drive imminent rate for that. And again we specifically designed this trial with a high-risk population and that was both a strategy of where we believe that Verzenio would really differentiate, but as well it drove the speed of the trial. So again we feel quite confident in that.

As you know, the positive MONARCH-2 overall trial results, particularly as we saw those with primary resistance and visceral disease really at eight months survival benefit in patients with visceral disease really reinforce our confidence in the potential success of monarchE. So we designed it with that high-risk population. And really used what we think are thoughtful selection factors that physicians use today to make prescribing decisions in that adjuvant setting. So things like the number of nodes involved the tumor size and the measure proliferation. And so we feel quite confidence in the design of the study and again, look forward to that readout in 2021.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks. Anne. Mike?

A - Mike Mason {BIO 18347681 <GO>}

Navin, thanks for your question on Humalog. The biggest driver in Humalog segment mix is the fact that with Humalog's uptake, they are taking volume away from Humalog in Medicaid, since our Medicaid rebate rates are essentially 100% that TRX decline actually doesn't have -- has a flat or positive impact on net revenues for Humalog.

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

And just to confirm the AG products are consolidated into that Humlog.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Navin, thanks for your questions. We'll go to Dave for the close.

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

Okay, thank you all. I appreciate your participation in today's earnings call and your interest in Eli Lilly and Company. 2019 was a strong year for the company. And we anticipate another great year in 2020. We remain focused on executing our innovation-based strategy to bring new medicines to patients and create value for our shareholders. With our strong commercial portfolio complemented by a pipeline of exciting opportunities Lilly continues to be a compelling investment. Thanks again for dialing in. Please follow up with our Investor Relations team. If you have any additional questions. We weren't able to address on today's call. Hope you have a great day.

Operator

Thank you. Ladies and gentlemen, this conference will be available for replay after 11:15 today, through January 30th, 2021. You may access the AT&T teleconference replay system at any time by dialing 1800-475-6701 and entering the access code of 2544079. Those numbers again are 1800-475-6701 and internationally 320-365-3844 with an access code of 2544079. That does conclude our conference for today. Thank you for your participation and for using AT&T Executive Teleconference. You may now disconnect.