

Eli Lilly and Company NYSE:LLY

FQ3 2017 Earnings Call Transcripts

Tuesday, October 24, 2017 1:00 PM GMT

S&P Global Market Intelligence Estimates

	-FQ3 2017-			-FQ4 2017-	-FY 2017-	-FY 2018-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	1.03	1.05	▲1.94	1.05	4.17	4.63
Revenue (mm)	5517.34	5658.00	▲2.55	5895.19	22489.81	22997.08

Currency: USD

Consensus as of Oct-24-2017 1:12 PM GMT

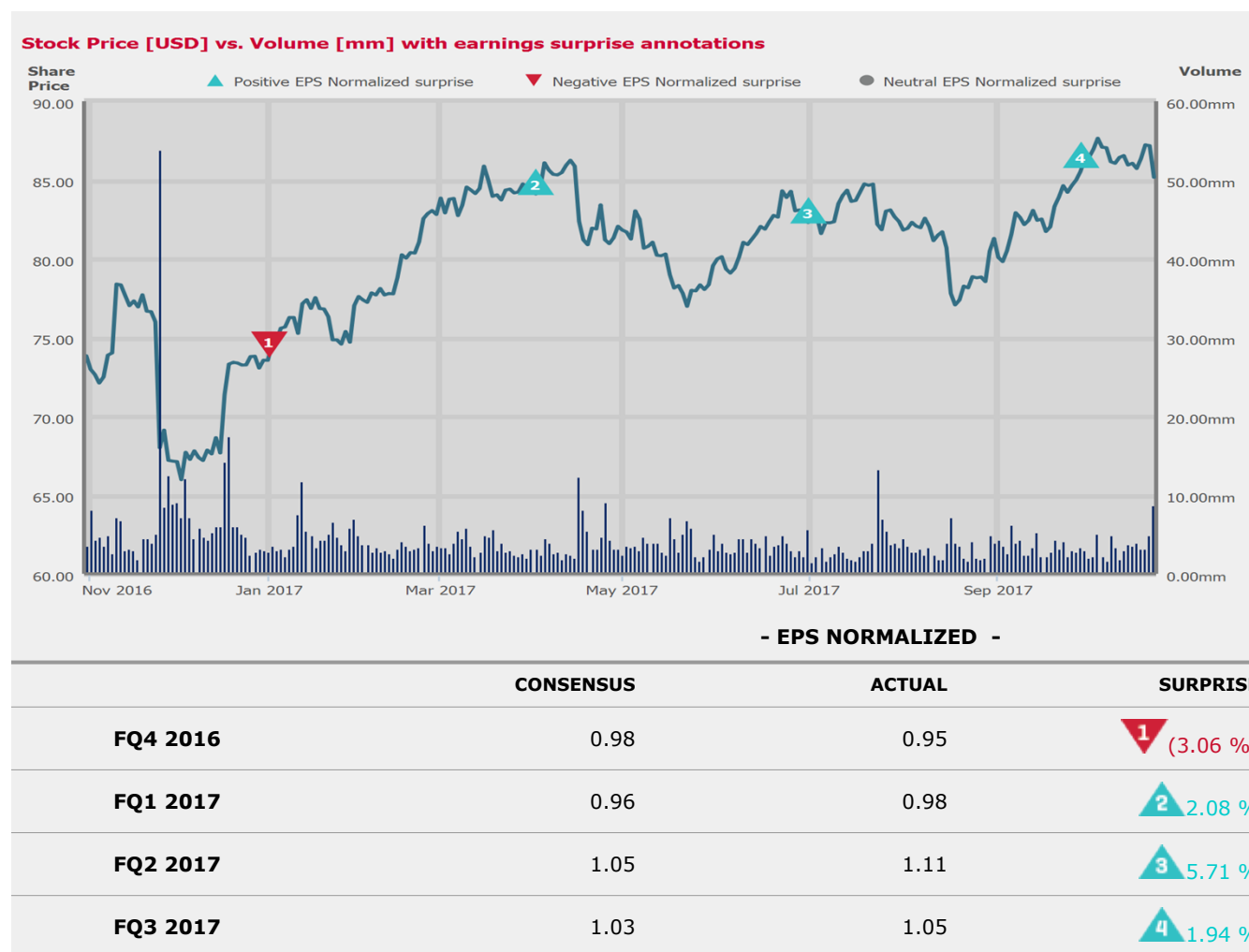


Table of Contents

Call Participants		3
Presentation		4
Question and Answer		8

Call Participants

EXECUTIVES

Christi Shaw

Senior VP & President of Lilly Bio-Medicines

David A. Ricks

Chairman, CEO & President

Derica W. Rice

Former CFO & Executive VP - Global Services

Enrique A. Conterno

Senior VP & President of Lilly Diabetes

Jan M. Lundberg

Former Executive Vice President of Science & Technology

Jeffrey N. Simmons

Senior VP & President of Elanco Animal Health

Joshua L. Smiley

Senior VP & CFO

Michael J. Harrington

Senior VP & General Counsel

Philip Johnson

Susan M. Mahony

Former Senior VP & President of Lilly Oncology

Unknown Executive

ANALYSTS

Andrew Simon Baum

Citigroup Inc, Research Division

Ardalan Arfaei

BMO Capital Markets Equity Research

Charles Anthony Butler

Guggenheim Securities, LLC, Research Division

Christopher Thomas Schott

JP Morgan Chase & Co, Research Division

David Reed Risinger

Morgan Stanley, Research Division

Geoffrey Christopher Meacham

Barclays Bank PLC, Research Division

Gregory B. Gilbert

Deutsche Bank AG, Research Division

Jamilu E. Rubin

Goldman Sachs Group Inc., Research Division

Jeffrey Holford

Jefferies LLC, Research Division

John Thomas Boris

SunTrust Robinson Humphrey, Inc., Research Division

Marc Harold Goodman

UBS Investment Bank, Research Division

Richard John Purkiss

Piper Jaffray Companies, Research Division

Seamus Christopher Fernandez

SVB Leerink LLC, Research Division

Stephen Michael Scala

Cowen and Company, LLC, Research Division

Timothy Minton Anderson

Sanford C. Bernstein & Co., LLC., Research Division

Umer Raffat

Evercore ISI Institutional Equities, Research Division

Vamil Kishore Divan

Crédit Suisse AG, Research Division

Presentation

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Q3 2017 earnings conference call. [Operator Instructions] And as a reminder, today's conference call is being recorded.

I would now like to turn the conference call over to your first speaker, Dave Ricks. Please go ahead.

David A. Ricks

Chairman, CEO & President

Good morning. Thank you for joining us for Eli Lilly and Company's Third Quarter 2017 Earnings Call. I'm Dave Ricks, Lilly's Chairman and CEO. Joining me on the call today are Derica Rice, our Chief Financial Officer; Josh Smiley, currently our Treasurer and the CFO-elect; Dr. Jan Lundberg, President of Lilly Research Laboratories; Enrique Conterno, President of Lilly Diabetes and Lilly U.S.A.; Dr. Sue Mahony, President of Lilly Oncology; Christi Shaw, President of Lilly Biomedicines; and Jeff Simmons, President of Elanco Animal Health. We're also joined by Kristina Wright, Chris Ogden and Phil Johnson of the IR team.

This will be the last earnings call for 2 senior executives that have been instrumental in our company's success. At the end of the year, Maria Crowe, President of Manufacturing Operations; and Derica Rice, our CFO, will retire. Maria has helped Lilly earn the trust of patients we serve by making medicines with the highest levels of quality and safety. Derica played a key role in leading Lilly for the challenging period of patent expirations we called Years YZ and emerging as a much stronger company. Both have built strong organizations that will carry on their work. So beginning here, please join me in a round of applause to thank both of them for their contributions to our company.

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 SEC.

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 it's not sufficient for prescribing decisions.

In Q3, we generated worldwide revenue growth of 9%, driven by volume growth in our human pharmaceutical business, once again, led by our newest products. I'd also highlight the outstanding performance of our diabetes products, which in total grew 39% this quarter.

We also continue to expand on our margins. Including the effect of foreign exchange -- excluding the effects of foreign exchange on international inventory sold, gross margin as a percent of revenue increased by over 70 basis points, and total operating expenses as a percent of revenue declined by over 310 basis points to 50.8%.

Our pipeline progress continued. Highlights include the FDA approved and we launched Verzenio, the U.S. trade name for abemaciclib for advanced breast cancer based on the MONARCH 1 and MONARCH 2 trials. We submitted the BLA for galcanezumab for migraine prevention, and we initiated the Phase III program for our ultrarapid insulin.

In terms of capital deployment, we entered into a global immuno-oncology collaboration with CureVac AG, focused on the development and commercialization of up to 5 cancer vaccine products based on CureVac's RNActive technology. And we returned over \$500 million to our shareholders through our dividend.

In other news, we received an important ruling upholding our Alimta method-of-use patent in the U.S. IPR proceeding. If upheld through all remaining challenges, Alimta would maintain U.S. exclusivity until May of 2022. Our performance in 2017 keeps us on track to achieve our midterm goals for each of our strategic objectives. Slides 5 and 6 contain more details on these events as well as other key events since our July earnings call.

I'd highlight that we've submitted abemaciclib for advanced breast cancer in Europe and Japan, and the U.S. FDA granted a priority review designation for the abemaciclib MONARCH 3 NDA. Along with Incyte, we announced that the NDA for baricitinib in RA will be resubmitted before the end of January '18. After further discussions with the FDA, we've also submitted the sNDA to include the KEYNOTE-021G data in the Alimta label. We announced a series of actions to accelerate our efforts to focus our resources on developing new medicines and improve our cost structure. And earlier this morning, we announced that we are reviewing strategic alternatives for our Elanco Animal Health business, including an IPO, a merger, sale or retaining the business.

Moving to our financial results. 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 insight into the underlying trends in our business. So please refer to today's earnings press release for the detailed description of the year-on-year changes in our third quarter GAAP results.

Looking at the non-GAAP measures on Slide 9, you can see the revenue increase of 9% that I mentioned earlier. Gross margin as a percent of revenue decreased to 75.1%. This decrease was primarily driven by the effect of foreign exchange rates on international inventories sold and negative product mix, partially offset by manufacturing efficiencies. Excluding the effect of FX on international inventories sold, gross margin as a percent of revenue increased by over 70 basis points.

Total operating expenses increased 3%, with marketing, selling and administrative expenses decreasing 1% and R&D expenses increasing 7%. As mentioned earlier, as a percent of revenue, OpEx declined by over 310 basis points. The decrease in marketing, selling and administrative expenses was driven by lower spending on late-life cycle products, partially offset by higher spending on our new products. The increase in R&D expenses was driven by a milestone payment related to the BACE inhibitor we're developing in collaboration with AstraZeneca and, to a lesser extent, higher late-stage clinical development costs.

Other income and expense was an expense of \$14 million this quarter compared to income of \$27 million in last year's quarter.

Our tax rate was 18.9%, a decrease of 310 basis points compared to the same quarter last year, primarily driven by a net discrete tax benefit this quarter of approximately \$30 million.

At the bottom line, net income and earnings per share both increased 19%. We achieved this significant earnings growth by delivering high single-digit volume-based revenue growth while significantly reducing our OpEx ratio, creating positive leverage.

Slide 10 details the same non-GAAP measures for September year-to-date, while Slide 11 provides a reconciliation between reported and non-GAAP EPS. You'll find additional details on these adjustments on Slide 24 and Slide 25.

Moving to Slide 12, let's take a look at the effect of price, rates and volume on revenue growth. The effect of foreign exchange was minimal this quarter. Excluding the slight headwind from FX, our worldwide revenue growth on a performance basis was 9% and was driven by volume, to a much lesser extent, by price. It's worth noting in our human pharma business, each major geography showed volume growth again this quarter. By geography, you'll notice that U.S. pharma revenue increased 10%, primarily driven by volume. Trulicity, Basaglar and Taltz were the main drivers of this growth, with recent loss of exclusivity leading to large volume declines for both Strattera and Effient. It's also worth noting that last year's third quarter included \$145 million benefit from a Cymbalta returns reserve reversal. Excluding this from the base period, our U.S. product growth was 17%.

Moving to Europe. Pharma revenue grew 7%, excluding FX, driven almost entirely by volume despite headwinds on Alimta due to generic erosion in certain countries as well as competitive and pricing pressures. Excluding Alimta, the rest of our European pharma revenue grew 13% on a performance basis. This was led by Trulicity.

In Japan, despite a large negative impact from the entry of generic Zyprexa last June, pharma revenue increased 13%, excluding FX. Excluding Zyprexa, the rest of our Japan pharma revenue grew 17% in performance terms this quarter, led by Cyramza, Cymbalta and Trulicity.

Our pharma revenue in the rest of world increased 9% on a performance basis this quarter, led by Humalog and Trulicity.

Turning to animal health. Excluding the impact of FX, worldwide revenue increased 4%, driven by volume. Food animal product revenue declined by 7%, while companion animal product revenue increased 34%. On a performance basis, excluding the BI U.S. vaccines acquisition and adjusting for last year's purchasing patterns, our animal health revenue decreased 10%, with food animal product revenue down 7% and companion animal product revenue down 17%. The food animal decline was driven primarily by market access pressure as well as by competitive pressure in U.S. cattle, while the companion animal decline was due to competitive pressures affecting Trifexis, our flea, heartworm and intestinal parasite product.

Slide 13 outlines the same information for our September year-to-date results.

Now let's look at the drivers of our worldwide volume growth on Slide 14. In total, our new products comprised of Trulicity, Basaglar, Taltz, Jardiance, Lartruvo, Cyramza, Olumiant and Portrazza, were the engine of our worldwide volume growth. You can see that these products drove 13.7 percentage points of volume growth quarter over the last -- the same quarter last year, while the loss of exclusivity for Cymbalta, Strattera, Effient, Axiron, Zyprexa and Evista provided a drag of 610 basis points.

Slide 15 provides a view of our new product uptake. In total, these brands generated over \$1.2 billion in revenue this quarter and now represent nearly 22% of our total worldwide revenue, up from just 18% last quarter.

Moving to Slide 16. As I mentioned earlier, changes in foreign exchange rates had essentially no effect on our Q3 2017 revenue growth. Similarly, FX had no meaningful impact on our operating expense growth. FX did, however, have a large effect on growth in cost of sales and, consequently, in operating income and EPS. For example, growth in non-GAAP EPS was 19%, including the effects of foreign exchange, and 30% in constant currency terms. This is consistent with the 28% growth we've seen year-to-date.

Now I'll turn the call over to Derica for a review of our overall corporate pipeline, progress on potential key events and an update on our 2017 financial guidance.

Derica W. Rice

Former CFO & Executive VP - Global Services

Thanks, Dave. Slide 17 shows select NMEs as of October 17. Movements since our last earning calls include the U.S. approval of abemaciclib for advanced breast cancer, the U.S. submission of galcanezumab for migraine prevention, the initiation of Phase III for our ultrarapid-acting insulin, the addition of a Phase I immunology asset from our recent collaboration with Nektar Therapeutics and termination of development of 2 Phase I assets.

Our select NILEX pipeline, shown on Slide 18, reflects the 3- and 4.5-milligram dulaglutide study and the negative outcome of the abemaciclib lung cancer study, JUNIPER.

Turning to Slide 19, you can see the considerable progress we've made on the key events we projected for 2017. Dave and I have already mentioned many of the key events that occurred since our last earnings call. So I'll simply comment on just one change. Following the positive data presented at EADV, we now expect to begin the Phase III program for baricitinib and atopic dermatitis before the end of this year.

Turning to our 2017 financial guidance on Slide 20. You'll see that we've raised and narrowed the range for revenue to \$22.4 billion to \$22.7 billion, primarily due to the uptake trends we're seeing for our new pharmaceutical products and, to a lesser extent, to a stronger euro. We've also narrowed the range for full year R&D expense to a range of \$5.1 billion to \$5.2 billion. We've decreased our GAAP and non-GAAP tax rate to reflect the tax effect of this quarter's business development and restructuring charges as well

as the discrete tax benefit mentioned earlier. For EPS, we've raised our non-GAAP EPS range by \$0.05 to \$4.15 to \$4.25 per share, and we reduced our GAAP EPS range to \$1.73 to \$1.83 per share.

Before we go to the Q&A session, let me briefly sum up. We've delivered another strong quarter in Q3. Led by our new products, worldwide revenue grew 9%. By making disciplined investments in our business, we leveraged our top line growth into 19% non-GAAP EPS growth or 30% growth when excluding FX.

We continue to have strong momentum behind our innovation-based strategy. Since our last earnings call, we received U.S. approval for and launched Verzenio. We submitted galcanezumab for migraine prevention here in the U.S. We started Phase III for our next-generation mealtime insulin, and we bolstered our pipeline with the CureVac deal.

We also announced [at ASH] to focus our resources on developing new medicines and to improve the company's cost structure as well as to review our strategic alternatives for our Elanco Animal Health business.

Going forward, our management team will remain focused on launching new products with excellence, reloading our late-stage pipeline, driving increased productivity to expand our operating margins and investing in our core drivers for our business: talent, scientific capabilities and technology platforms, to ensure our future growth prospects.

This concludes our prepared remarks. Now I'll turn the call over to Phil to moderate the Q&A session. Phil?

Philip Johnson

Thank you, Derica. [Operator Instructions] Now, Alan, if you can go ahead and provide the instructions for the Q&A session, we're ready for the first caller.

Question and Answer

Operator

[Operator Instructions] First question will come from the line of Tim Anderson with Bernstein.

Timothy Minton Anderson

Sanford C. Bernstein & Co., LLC., Research Division

On Trulicity, an important growth driver, you guys called it out, a major future growth driver. I'm wondering if you can just give us your thoughts on the curve of that product as we go into 2018 because you are facing new branded competition from Novo's weekly product. They've had some compelling head-to-head data. I'm wondering how you think that might impact your product. And equally importantly, they have their oral GLP-1, they have several Phase III readouts coming in 2018, and I'm wondering if you can give us your opinion of the viability of that program. It seems that if they had a good clinical profile, that could be problematic for injectable GLP-1s. Or do you think the clinical profile of that product will, in fact, be problematic? And then on Humalog, no biosimilar yet approved. You guys have, I think, a patent that you could potentially assert and leverage into a delay or maybe a settlement with Sanofi. Can you give us any update there?

Philip Johnson

Great. Tim, thank you for the questions. So Enrique, we'll go to you for the questions on Trulicity heading into '18 with new branded competition coming and thoughts on the oral GLP-1 space. And then we do have our General Counsel, Mike Harrington, with us. So Mike, if you'd like to give the update on litigation with Sanofi. All right, Enrique?

Enrique A. Conterno

Senior VP & President of Lilly Diabetes

Very good. Well, thank you for the question. And indeed, Trulicity is having a terrific year. It's a unique time when it comes to innovation in diabetes. And let me try to maybe frame some comments and provide some color as we think about Trulicity going forward. I will not provide an outlook for the product but some things to think about. The biggest opportunity for Trulicity is -- when we think about this class is that -- and when we look at injectables, GLP-1s as a class still represent less than 30% of the basal insulin prescription. We see significant benefits when it comes to the GLP-1 class, so the opportunity for growth is very significant. Trulicity has an enviable position in this market by the benefit that it basically offers when it comes to the real-world efficacy of the product, of course, the once-weekly dosing. And we have a single-dose pen that is ready to use and that does not require basically managing or seeing the needle, which is so important for a patient that is transitioning, in many cases, from an oral medicine. Now, clearly, we do have competition, yes. But I think what we have to keep in mind, too, is that the competition is also going to help fuel the overall growth of the class. The class has very healthy growth, and we expect that, that's going to be a continued catalyst for Trulicity as we think about the growth of the class and the type of position that we have in the market. Our trends continue to be very solid for the product. Clearly, when it comes to sema, we'd like to see all of their data when it comes to SUSTAIN 7, but we feel good about the position that we basically have when we look at the -- both the combination of our efficacy and the safety profile that our product offers. You asked about oral GLP-1s. That is an area of interest to us. We do see the innovation in the space as important, but we need to wait for all of their data to basically come out before we can make more comments. And then I believe that Mike is going to comment on Humalog.

Michael J. Harrington

Senior VP & General Counsel

Thanks, Tim, for your question. The deadline under the Hatch-Waxman Act for Lilly to challenge Sanofi has expired, and we have not filed suit to challenge their follow-on biosimilar. As you know, Tim, the Hatch-Waxman Act notice process provides an opportunity for a company to carefully assess whether a

follow-on product infringes patents listed in the Orange Book for a particular product. The only remaining Orange Book-listed patent that we have that is relevant to this discussion protects our KwikPen delivery device, and we have thoroughly analyzed both the Sanofi device and our own device. Lilly's KwikPen is a innovative device that offers a number of advantages for patients, but for purposes of analyzing the patents, it's a fundamentally different device than the Sanofi pen that they intend to use with their follow-on lispro. We always vigorously defend our intellectual property and will continue to do so aggressively, but we don't engage in litigation to enforce patents unless there is a factual and legal base to do so. And here, we didn't have a factual and legal basis to support litigation.

Philip Johnson

Great. Mike, thank you for the update.

Operator

Dave Risinger with Morgan Stanley.

David Reed Risinger

Morgan Stanley, Research Division

My first question is with respect to the animal health business. So you've announced that you're exploring strategic alternatives. Could you just provide a little bit more color around the timing, why now? I know that this is something you've contemplated for years, but the business' organic growth hasn't been inspiring recently. And so it'd be helpful for you to just provide a little bit more color about why now and how you see the business' organic growth prospects going forward. And then second, with respect to Forteo, I believe there may potentially be generic entry in the U.S. and Europe in 2019, but it would be helpful to get your perspective on how investors should think about the generic threat to Forteo in 2019.

Philip Johnson

Okay. Dave, thank you for the questions. So Dave Ricks, if we can have you answer the question on alternatives that are being explored and timing for the Elanco Animal Health review. And then, Christi, if you want to comment on the outlook for Forteo post-generic entry.

David A. Ricks

Chairman, CEO & President

Great. Thanks, Dave. We haven't touched on the short-term operational things, and we may get other calls on that. I mean, it is true, we've had some challenges in the business this year. We don't look at the question of how we should position Elanco in the short term; we think of it as the long term. And we've been, as you point out, asked this question for a long time. It's a natural one to ask. What -- I think where we think we are now, why now, is over the last many years, we've grown this business rather substantially through acquisition but also through our own organic actions. And we now have a global business that's highly competitive. It's a top-tier animal health business, amongst the top 5 globally, and we participate in all of the relevant segments of animal health, most recently combining BI's vaccine business in North America coupled with Novartis. And it's taken some work to fully operationalize and get those companies pulled together in a way that we think where this company is at least poised to compete effectively and really grow aggressively ahead. And so now is a good time, having completed those acquisitions and scaled the business, to reflect on the best posture for Elanco Animal Health. And as we said today, we're exploring options. We expect to be able to get back to investors by mid-'18 with the results of our analysis. And the full range of options are in scope, keeping the business, IPO or spin or perhaps some other combination that we might determine is the best way to maximize the value to Lilly shareholders. So we'll follow up with you as that process progresses, but we think this is a good time to step back and look at this question.

Philip Johnson

Thanks, Dave. Christi?

Christi Shaw

Senior VP & President of Lilly Bio-Medicines

Yes. On the Forteo question, we continue to be very pleased with the performance of Forteo, and the data continues to support how strong it is in the fracture prevention and treatment. And so as we look at Forteo in the future, we do have the same estimate as you do, which is the expiration of the patent being in 2019, and that's across U.S., major Europe and Japan. Obviously, it is difficult to make. Forteo is not easy. So that will really be the question mark, and -- but our estimates are that 2019 is when we'll lose that intellectual property protection.

Philip Johnson

Great. Thank you, Christi.

Operator

Andrew Baum with Citi.

Andrew Simon Baum

Citigroup Inc, Research Division

A couple of questions. I'm surprised you haven't used your balance sheet for more substantial...

Philip Johnson

Hey, Andrew...

David A. Ricks

Chairman, CEO & President

I can't hear him.

Philip Johnson

It's very low volume, and it's cutting in and out a bit.

Andrew Simon Baum

Citigroup Inc, Research Division

Let me try that. Does anybody...

Philip Johnson

Thank you. Yes.

Andrew Simon Baum

Citigroup Inc, Research Division

Terrific. So I was saying I'm surprised that I haven't seen Lilly use their balance sheet for any more substantial business development within oncology given the reshaping of the business. Could you just maybe share a little bit of color, is that a question of the bid-ask spread? Is it available assets? Is it a clinical base that needs to be turned over? What is potentially delaying that? And the second, the relative performance of Taltz versus your competitor, COSENTYX, especially in the last quarter would seem to disfavor Lilly. Could you outline what are the in-market dynamics that are driving this disproportionate marketing and how you're thinking about adjusting going forward?

Philip Johnson

Great. Andrew, thank you for the questions. Derica, if you'll address the question on using our balance sheet for business development in oncology and then the impediments we're seeing to actioning that. And then Christi to comment on dynamics with Taltz and COSENTYX in that market. Derica?

Derica W. Rice

Former CFO & Executive VP - Global Services

Sure. We have no apprehension or reservations about using our business -- our balance sheet to pursue our therapeutic goals, whether it's in oncology or across our other therapeutic segments in which we compete. And we do continuously look at the marketplace for external asset opportunities that we'd like to pursue. Most recently, you've seen just this year, 3 years in the -- 3 deals in the area of oncology. Now all of those are early-stage deals, and that's by design. That's the area that we've chosen to focus on. If we can find late-stage assets like we did with CoLucid at the beginning of this year, we'll pursue that as well. In regards to market prices, oncology still is very expensive real estate, and one of the things we have to make sure that we do in protecting our shareholders is that we do good diligence on those opportunities we look at. And sometimes it is tough finding value in some of the assets at the market prices at which they're being touted. So that's something we've been cognizant of, and that's why we've chosen to go -- look to go earlier rather than later if we can.

Philip Johnson

Great. Thanks, Derica. Christi?

Christi Shaw

Senior VP & President of Lilly Bio-Medicines

Yes. Andrew, so on Taltz, we continue to be very pleased with the performance of Taltz, especially as we see patients with clearer skin. And as you look at the dermatology office, defining our competitors really is not the IL-17s versus the IL-17s. What you see is really the TNFs under -- really not reaching that clear status. And the more we have new agents like the IL-17s and the newer agents that are coming out, the more that we'll see the expectations of both physicians and patients increase. A couple of those details for you on what you're seeing in the numbers. If you look at the data, there's a couple of things. One is COSENTYX has added 3 goods to their NBRx data. So IMS tells us there's a lot of volatility in that data, and it will take weeks for that to -- or maybe even months for that to actually level out. So what we're looking at is actually the net sales. And if you look at net sales in the U.S. in the dermatology office, we are performing the same as COSENTYX was at the same period of time, which is pretty remarkable for a second entry into the market. And usually if you have 80%, that would be great, but for us to be able to do that. So we continue to feel very good about it. The other thing to note is we do see seasonality in the summertime. So as you look at specifically in the dermatology office with psoriasis, that's where you'll see the seasonality. You don't see that with psoriatic arthritis or ankylosing spondylitis. So that is another thing that's kind of clouding the numbers as you see the seasonality more affect our numbers because we're only in the dermatology office right now. And then as you look into the future, we're very excited to hear from the FDA by the end of the year, which as we continue to see the breadth and depth of prescribers continue to increase, we see our early adopters increasing their number of prescriptions, we see more physicians trying Taltz with the psoriatic arthritis launch and our entry into the rheumatology office in December and January. Given FDA approval, we should see another step-level increase in Taltz. So we're very confident and continue to believe in the Taltz performance.

Philip Johnson

Great. Thank you, Christi.

Operator

Jami Rubin with Goldman Sachs.

Jamilu E. Rubin

Goldman Sachs Group Inc., Research Division

Just a couple of follow-up questions. First, on Dow Elanco, could you remind us, Dave, what the operating margin is on that business? I seem to recall that's a lower-margin business than your base business, but your overall operating margins at around 22% or so are well below the industry average. So if you contemplate spinning that business or selling that business, can you talk sort of generally about what impact you would see that having on your overall margins? And then secondly, just given the opportunity to take advantage of the risk or of the PE overcharge given where Zoetis is trading, what do you think you will do with those proceeds? And just if I can ask a question about the cost-cutting announcement

that you made a couple of months ago, the 3,500 positions that you are reducing, that has generated some debate among investors regarding your confidence in your ability to hit your sort of mid-single-digit top line growth projection over the intermediate term. Can you shed a little bit of light on the reasons for the additional cost-cutting program? I know that should lead to an improvement in operating margins, but should we think of this as an insurance policy against the top line growth opportunity? Or is this -- or should we look at this as above and beyond what the company expects to perform -- how the company expects to perform going forward?

Philip Johnson

Okay. Jami, thank you for the questions. If I can, I'm going to reorder our answers just to sort of get the flow going here. So Dave, if you wouldn't mind handling the headcount reduction question, the last one Jami had, first. You're going to provide any comments on Elanco margins then. Jeff, feel free to complement that answer if you'd like. And a little bit of Derica for the question around use of proceeds, if we're having the transactions yielding proceeds in the future. Dave?

David A. Ricks

Chairman, CEO & President

Sure, yes. Thanks, Jami. I mean, you used the Dow Elanco name. That's harkening back to the old days. So this is just Elanco now, but appreciate the questions. Let me -- on the cost-cutting, so we announced this in early September. This has no relation to our belief about the revenue line, just to be clear. What we're looking at is looking beyond our -- what we long held out, this 2018 target of 15% operating expense as a percent of sales. And we've said for some time qualitatively that, that was a stepping stone on the way to a more productive, higher-operating margin company. These actions put us further down that road. That's how we're thinking of them, both to become more competitive with our operating margins but also to free up cash flow and operating spend capacity to invest in R&D. We see a number of late-stage projects that have read out positively more than we expected. They're now launching, but we need to invest behind those with important new indications in other uses, like Verzenio in the adjuvant setting, like Olumiant in atopic dermatitis like we spoke about today. So that's what it's for. It's about our quest to become even stronger for the future, nothing to do with our conviction on the 5% revenue growth, which I remind investors we did 9% again this quarter, so -- and we continue to trend above that CAGR we committed to. And although we know '18 will be facing some more generic events, we're very confident on the 5% by 2020. So with that, let me turn it over to Jeff on the Elanco operating margin story. We can compare that to Lilly afterward, and Derica, if you could comment on the balance sheet.

Jeffrey N. Simmons

Senior VP & President of Elanco Animal Health

Yes. So Jami, just on our margin, as we've shared pretty openly with -- as we've come to the integrations of Novartis as well as Lohmann and now BI, we've been hovering around 20% for the past 2 years. We feel good about our -- not only this assessment but our strategy going forward on our margin expansion opportunities, as we've been pretty open about. And we've got a pretty aggressive agenda. We announced 2 events this quarter that are part of that agenda, that is well underway. And the first was our consolidation of our Larchwood, Iowa manufacturing facility into our Fort Dodge, the BI acquisition facility, as well as we're seeking options for our bST. The 2 big drivers that give us this current state is no question, some of the forces in the lower sales and the other's product mix. And we are -- we're working aggressively not only to drive these margins closer, as we've said, to the 30% over time -- that will not happen here in the short term but over time. That'll happen by both the margin expansion productivity agenda as well as the innovations that drive our product mix change.

Philip Johnson

Thanks, Jeff. Derica?

Derica W. Rice

Former CFO & Executive VP - Global Services

Jami, in regards to potential proceeds, we haven't gotten that far in our thinking. Right now, what we're really focused on is what's the best path forward in terms of maximizing the value of the animal health asset on behalf of the Lilly shareholders. And as Dave highlighted, we'll look at that full array of options before us. That having been said, even back to the earlier question that Andrew asked, we have the balance sheet capacity today to pursue the types of opportunities that we're interested in. So while we're contemplating these strategic alternatives for Elanco, it is not inhibiting us or preventing us from moving forward with our current organic and inorganic strategy in terms of assets we want to pursue. So we're still moving full speed ahead. And as Dave highlighted earlier, back to your 5%, over the last 3 years, recall when we gave the guidance in 2015, we've averaged, in terms of top line growth, somewhere between 9% to -- 7% to 9% in each year. And this year, as Dave said, we're tracking towards 9% growth. So we're very confident that we can meet that minimum threshold of 5% for the decade, which takes us out through 2020, and we think we're actually well on track to achieve that.

Philip Johnson

Thanks, Derica. Jami, thanks for the questions.

Operator

Umer Raffat with Evercore.

Umer Raffat

Evercore ISI Institutional Equities, Research Division

I wanted to focus on a couple of things. One, on baricitinib perhaps, just curious what your confidence is on the 4-milligram dose in particular. And then secondly, just touching up again on lispro, a, can you confirm -- and I heard the prior comments, but can you confirm that there's no settlement at present between you and Sanofi on the lispro launch? And then also, how do you think about lispro launch? And in theory, how should or shouldn't it be different than Basaglar versus Lantus?

Philip Johnson

Great. Umer, thank you for the questions. I assume with the 4 milligram, you're referring to the ongoing review at the FDA for our rheumatoid arthritis application, is that correct?

Umer Raffat

Evercore ISI Institutional Equities, Research Division

Correct.

Philip Johnson

Okay. So Christi, we'll go to you for the question on the baricitinib 4 milligram. Mike Harrington, if you'd like to comment on whether or not there's any kind of settlement with Sanofi. And then, Enrique, for the dynamics that you could -- might think about for the launch of lispro whenever that occurs here in the future. Christi?

Christi Shaw

Senior VP & President of Lilly Bio-Medicines

So I think it's important, as we discuss the 4 milligrams of baricitinib, to see, well, how is it doing, where we are commercializing the 4 milligrams. As we look at Europe, for example, specifically in Germany, the launch in Germany not only exceeds our internal expectations, but as you look at the 5 months in which it's been available, it has exceeded every rheumatoid arthritis launch in history, including Humira. So as we look at that uptake in the 4 milligrams is the majority of the use, and we see what the patients are seeing and coming back to their offices where they were debilitated, they've tried other agents, and they've gone on baricitinib, and really, things like in Japan, they're now able to drive where they haven't been able to before, it's really life-changing. So as we look at the U.S. and our discussions with the FDA and the ongoing conversations we continue to have, the 4 milligrams is imperative for these patients to get the benefit and the efficacy that they need to be able to go about their daily lives. So it is still

our strategy, that we believe in the 4 milligrams. We're seeing it play out in the real world, and we look forward to having the resubmission. And it will -- it is on track to happen before the end of January, as we had mentioned in the past. And then after that, we'll have the 6-month clock in which we'll get a read, but we're very optimistic.

Philip Johnson

Thanks, Christi. Mike?

Michael J. Harrington

Senior VP & General Counsel

And Umer, I can confirm there is no settlement agreement in place between Lilly and Sanofi related to their follow-on lispro.

Philip Johnson

Okay. Thanks, Mike. Enrique?

Enrique A. Conterno

Senior VP & President of Lilly Diabetes

So there are a few things to consider when we basically compare and contrast the basal insulin situation vis-à-vis mealtime insulin. And when we enter, of course, with Basaglar and all of the learnings that we got there, and then hopefully, we can apply those learnings in reverse in a certain way. So first, the basal insulin class is -- was significantly more open at the time that Basaglar entered. So we've had a number of different basal medicines in formularies, and that's relative to the mealtime insulin space, where most formularies are really under exclusive status, and that leads to lower prices. So the situation today and the economics for the payers today are such that it was easier to create viable economics for the payer in the basal insulin space relative to where we are in the mealtime insulin space. Two, is that in the case of Humalog, we have a full range of formulations, not just Humalog but Humalog mixtures. We have a concentrated mealtime insulin, Humalog U-200. And we recently even just launched the Humalog KwikPen Junior, which basically is the first half-unit prefilled pen in the market. So we're excited by that offering, and we do believe that our offering places -- gives us some strength when it comes to a follow-on lispro just coming into the market. Of course, it's additional competition, and we have to see when will they launch. It is likely that they had to resubmit, of course, to get final approval, and we are -- that's probably a question from a timing perspective for Sanofi.

Philip Johnson

Great. Thank you, Enrique.

Operator

Tony Butler with Guggenheim Securities.

Charles Anthony Butler

Guggenheim Securities, LLC, Research Division

Enrique, back to Trulicity, if I may. To what degree is the growth due to switches from Victoza versus that from orals straight to Trulicity? Part B of this is, does or would diabetic retinopathy actually cloud the class, assuming that's part of the warning of semaglutide in the label? And then the second question is really around abemaciclib in non-small cell lung cancer. While one trial did not show OS -- and I'm curious, your confidence on the other trials, specifically in non-small cell lung cancer.

Philip Johnson

Great. Tony, thank you for the questions. Enrique, the first 2 for you on the source of Trulicity's growth as well as if the diabetic retinopathy that was seen in one of the Novo studies might impact the overall class. And then, Sue, over to you for a discussion on other trials that are ongoing for abemaciclib in non-small cell lung cancer. Enrique?

Enrique A. Conterno*Senior VP & President of Lilly Diabetes*

Very good. When it comes to the source of Trulicity growth, I think it's important to highlight that our strategy from the very beginning was not to focus on current GLP-1 users. So most of our strategy has been on additional adoption by specialists and then really the breadth in primary care. I believe that strategy has been highly successful, so this is a source of our business by a very significant amount. I don't have the actual figures with me, but it's minimal, whatever we get in terms of switching from other GLP-1s. We'd like for that to continue given the opportunity when it comes to patients on oral medicines that could benefit from better control. When it comes to retinopathy, the data for Trulicity, I think, is very clear, and we do not have a signal when it comes to retinopathy. We have to see how a potential warning or how the labeling of retinopathy for semaglutide will basically read out. But clearly, we see significant advantages of GLP-1s in general, and we are counting on significant growth of this class as we think about Trulicity. I think that is the -- probably the -- one of the most important drivers of overall value for this asset.

Philip Johnson

Thanks, Enrique. Sue?

Susan M. Mahony*Former Senior VP & President of Lilly Oncology*

Yes, sure. Tony, with regards to the JUNIPER study, which was abemaciclib in KRAS mutation-positive advanced lung cancer, we did not see an overall survival advantage, I should mention. We did see, though, interesting single-agent activity in progression-free survival and overall response rates. And this is the first study that has been prospectively looking at erlotinib in KRAS mutation-positive breast cancer. And without giving you full data, we did use historical control and had assumed based on historical in total about a 6.5-month overall survival with erlotinib. We saw higher than that. What -- we are continuing to progress, though, other studies in lung cancer, and we continue to be confident in those, particularly around rational combinations. We do believe, particularly with regards to KRAS mutation-positive lung cancer, which is really hard to treat, that rational combinations will be important. And we've got a number of those ongoing, including IO combination with abemaciclib in combination PI3K/mTOR, and also we've got a Phase II squamous cell lung study ongoing.

In addition to that, we're looking at other tumors as well. And so our life cycle plan continues to look at progressing abemaciclib Verzenio now in breast cancer but also in other tumor types.

Operator

That will be Marc Goodman with UBS.

Marc Harold Goodman*UBS Investment Bank, Research Division*

If we look in the Phase II pipeline there, there's 8 products. I think, many of us know the BACE, but several of the others are not as well known. Can you just talk about some of the products and where we should be focused? And what kind of data we should be expecting? And where there's excitement there? And then just secondly, on Basaglar, it had a very strong uptick relative to the [script] trends. So I was just wondering if there's any stocking or anything unusual in inventory change there.

Philip Johnson

Marc, thanks for the question. So Jan, if you'd like to take a lead on the Phase II pipeline question. Others feel free to augment that answer if you'd like. And Enrique, anything unusual in the quarter on the Basaglar numbers, if you can comment on that. Jan?

Jan M. Lundberg*Former Executive Vice President of Science & Technology*

Okay. So let me start in immunology with [indiscernible] or IL-23 P19 antibody, which is tested in psoriasis as well as the 2 IBD indications: ulcerative colitis and Crohn's. And we are expecting data late -- well, early next year, the first half or particularly psoriasis would come first. In immunology, we also have the oral BTK inhibitor, the Bruton tyrosine kinase, which we are testing in RA with also data coming next year, and we are interested, clearly, because it's another potential oral agent in the immunology space. For diabetes, we have 2 agents. The first one is GIT GLP-1, it's the dual agonist then of 2 different mechanisms to lower body weight and also having potentially a better glucose control. We are particularly interested in this agent since in preclinical models, it has actually better intake than any other GLP-1 agent studies including semaglutide. The [indiscernible] is another variant and also [indiscernible] like molecules with the Amylin and also the calcitonin stimulating receptor agent. And the reason here is to have not only body weight lowering, but also potentially insulin sensitization activity. And clearly, these 2 agents are somewhat in parallel for readouts, and we also have high-dose dulaglutide coming about the same time, and then I think we will make a choice about what is the next potential Phase III then in the insulin space. The BACE inhibitor, we also have in Phase II, is a very potent oral agent that has potentially less peripheral issues in relation than to targeting Phase II. And we are actually running this also as a kind of a backup to lanabecestat, as you know, which is in Phase III. And we're also considering potential combinations of this BACE inhibitor with N3pG in preclinical models, that has been shown to have extraordinary clearance on not only plaques but also diffused amyloid. Perhaps Sue can talk about the oncology space.

Susan M. Mahony

Former Senior VP & President of Lilly Oncology

Sure. Well prexasertib, we have in Phase II in ovarian cancer. We are specifically looking at developing this medicine and looking at biomarkers. So first, you look at ovarian cancer and then we will progress, hopefully with the biomarker driven registration study should the Phase II data warrant that. Merestinib, we are developing actually this medicine in biliary tract cancer. We have a study for both Cyramza and merestinib in biliary tract cancer. Depending on the data on the Phase II on that, we would progress one or either, potentially both, but probably one or either of those medicines in that indication. And PI3K/mTOR inhibitor, we're really developing that as a combination therapy, and we have, as I'd mentioned earlier, a combination of PI3K/mTOR with abemaciclib.

Philip Johnson

Great. Thank you. Enrique, on Basaglar?

Enrique A. Conterno

Senior VP & President of Lilly Diabetes

Sure. We're very pleased with the performance of Basaglar and the continued adoption of Basaglar as a key basal insulin. When we look at the quarter, I think there's nothing on the stocking side but there was \$12 million worth of a benefit related to changes in rebates and -- of the estimates of rebates and discounts for prior periods.

Philip Johnson

Great. Thank you, Enrique.

Operator

Seamus Fernandez with Leerink Partners.

Seamus Christopher Fernandez

SVB Leerink LLC, Research Division

So just a couple here. You guys have obviously evaluated the Elanco potential spin for quite some time. Didn't want to talk a little bit and just kind of get your sense of -- in the current market we've seen companies make these types of announcements and then it takes a longer period of time to actually execute on the spin and then new results and disappointment. Just trying to get a sense of your commitments to offering a definitive conclusion as of the middle of 2018, as you stated in your press release. And if we could, just to get a sense, I think the spin is fairly obvious, but historically, most

companies have talked about the synergies between the business. Dave, I was just hoping you could talk about, if you see those synergies in the business any longer given the evolution of Lilly's business. And then my second question, we did see a few additional VTEs announced for a competitor JAK inhibitor in an ACR abstract. I wanted to know if there's been any change in the frequency or rate of VTE that you've seen in any of your clinical data? Or if it's still consistent as part of the resubmission, if it's consistent with the rates that we've seen in the past, which I believe you've stated are consistent with the historical rates of VTE for patients with RA?

Philip Johnson

Shamus, thank you for the question. So Dave, we'll go to you for the first couple of questions on -- we'll be able to provide a definitive answer by mid '18 on the strategy for Elanco going forward. And your view on synergies with that business. And then over to Christi to talk about the rates we're seeing of VTE in our program with baricitinib.

David A. Ricks

Chairman, CEO & President

Shamus, thanks for the questions. Of course, we came out today and said mid '18 because that's where we believe we're going to hit. So that's our best estimate of being able to get back to investors. And we think that's ample time to evaluate the questions before us, as we look at the options to maximize the value of this asset and over the long term. So that's our focus and I wouldn't wobble from that. Certainly, today, in day 1, I think this is a business that has been -- it does have some synergies with core Lilly but primarily it's operating outside of the core business of a Lilly. There's some back office synergies we gained and of course, we've talked through time about the R&D synergies. Although as we looked into that, I think they are currently rather modest. One reason for that is the platforms used across animal health are different. We have a large vaccine portfolio that doesn't synergize with pharma R&D today. We have a feed additives business that has really no synergy connecting to Lilly. On the companion side, therapeutics, that has some potential, but as we've looked at this, I think there's no reason to believe we couldn't maintain some of the synergies contractually if we had a different structure. So we're looking at all this and midyear next year is our deadline.

Philip Johnson

Thanks, Dave. Christi?

Christi Shaw

Senior VP & President of Lilly Bio-Medicines

Sure. In regards to thromboembolic events with baricitinib, we continue to monitor the real world evidence where we've launched commercially as well as accumulating data for our resubmission. As you know, the last time we submitted was January of 2015, so we have much more data to resubmit. And everything that we've seen, we've seen nothing in our atopic dermatitis studies. And everything is consistent, as we've said before, with normal background rates in the rheumatoid arthritis patient population. So no new news to report there.

Philip Johnson

Great. Thank you, Christi.

Operator

Chris Schott with JP Morgan.

Christopher Thomas Schott

JP Morgan Chase & Co, Research Division

Just a couple of questions here. I mean, first on Jardiance dynamics, you've obviously seeing fairly healthy share gains. When we're thinking about overall category growth, are you happy with the trends we're seeing there? And what do you think is going to take to further expand usage of the class overall? My

second question was a broader-diabetes question. I know each segment is different, but just as we've gotten maybe further into contracting season, et cetera, just any preliminary comments about 2018? Are there pricing or access to the portfolio? Anything we should just be keeping in mind as we think out to next year? And then my follow-up question was on Elanco as we think about strategic options. Do you believe further consolidation among the large animal health players is possible from an antitrust perspective as we think about the various kind of options that you're considering with this strategic review?

Philip Johnson

Chris, thank you for the questions. Enrique, the first couple for you on Jardiance particular classic growth, potential catalysts for that going forward. And then the diabetes 2018 access picture, to the extent you can comment. And Dave, if you can talk through the question on the Elanco consolidation and the animal health industry question. Enrique?

Enrique A. Conterno

Senior VP & President of Lilly Diabetes

So Jardiance has pretty quickly become the new standard when it comes to initiating patients on an SGLT2 therapy. Our share now in -- when it comes to new-to-brand prescriptions is now north of 50%. And the overall trends, when it comes to volume or share, I think are very strong. Of course, when we look at the class, we do see some dynamics to the -- related to the overall leader of the class. But as we think about the long-term opportunity for this product, we need to focus much more on Jardiance than on the class and the trends that basically Jardiance can continue to have. Clearly, the opportunity is enormous. Let's keep in mind that there are 160 million prescriptions written for oral medicines in the United States and SGLT2s have only 10 million of those. And we are basically looking at a product that has an indication to reduce the risk of cardiovascular death for people with type 2 diabetes and established cardiovascular disease, which we believe is about 30% or so of the people with diabetes. So the opportunity is enormous and we are thinking of that opportunity with Jardiance in mind. When it comes to 2018, and as we think about pricing and access, I think, clearly, the different pharmaceutical benefit managers have already announced their formularies, but we do see a continuation of the trends when it comes to pricing pressures in diabetes. There was one notable exception that we saw that we were surprised and that was the exclusion of Jardiance from the CVS health formulary. We, of course, are very disappointed with this decision, and we don't believe this is in the best interest of patients given the profile of Jardiance from a safety perspective and the label when it comes to cardiovascular and the fact that a competitor has a black box related to amputation. So we'll make our case with the physicians and with the patients.

Philip Johnson

Thanks, Enrique. Dave?

David A. Ricks

Chairman, CEO & President

Yes, so Elanco is a combination, still possible in the sector, obviously, and we obviously have a lot of combinations, we've been a part of that. But to answer the question, really have to look at the facts of the combination you might be looking at. So I guess, yes, it's possible, but we need to look at the product mix that would be resulting in any combination and then determine the antitrust risk. We do think that's an avenue but we'd have to look at the facts in each geography.

Philip Johnson

Thanks, Dave.

Operator

That will be John Boris with SunTrust.

John Thomas Boris

SunTrust Robinson Humphrey, Inc., Research Division

First question just has to do with abemaciclib. Listening to the Novartis call this morning, it certainly seems as though the launch of Kisqali has certainly underwhelmed Novartis. What have you learned from the Pfizer and both the Novartis launches relative to the profile of abemaciclib as we track this product going forward here that gives you confidence that it will have some relatively robust uptake? And then second question just has to do with pricing in particular. Questions we get all the time are the difference between gross to net and the FDA's approval of so many innovative agents in therapeutic categories that over time is going to lead to an increase in the gross to net differential as discounting and rebating plays a much greater role. Dave, how do you think about the business especially your most profitable affiliate, the U.S., in managing that going forward, to add some comfort to investors who take a long-term view and invest for the long term? And then on the patient front, obviously, a lot of discounts and rebates certainly aren't passed onto customers as their deductibles and their co-pays are going up. What's the potential solution? Is there one out there to potentially ensure that a greater amount of that discount or rebate gets back into the customer's pocket so they can afford the new innovative medicines that you have here going forward?

Philip Johnson

Thank you for the questions, John. So Sue, we'll go to you for the things we've learned from the IBRANCE and Kisqali launches. We think about launching Verzenio. And then Dave, the questions on managing the U.S. market, particularly the dynamics that we brought by more branded agents being approved in causing competition as well as what solutions there might be to help with the patient side of the equation where a lot of the cost increases have been occurring. Sue?

Susan M. Mahony

Former Senior VP & President of Lilly Oncology

Yes, John, thanks for the question. Clearly, it's early days. There's only been a few weeks out in the market with Verzenio. But we are very pleased with what we're hearing so far and our progress to-date. We can't give you any quantitative data because of timing, but from a qualitative perspective, we are seeing our milestones on access being achieved. We got the channel access ahead of plan just a few days after approval. We've seen hospitals and pharmacists stocking the product and actually patients being started. What we're trying to do is to ensure that access is as easy as possible for patients and also that the first experience that patients and physicians have with Verzenio is good. What we are hearing is that the differentiating factors for Verzenio are resonating. The single agent activity is a differentiator for Verzenio. Also, the fact that we can continuously dose, we've been very proactive from a side effect and safety profile. People are very appreciative of that and are telling us that the diarrhea is manageable. We're providing loperamide and support around that and people are very appreciative of that and saying it's manageable. What we are -- what we're hearing from physicians is that they see Kisqali more like palbo, and that we have some differentiating features that they think are important and clinically relevant. So I'm very interested in giving you an update as we get further down the launch of Verzenio here in the U.S. Just on that, we've also submitted to Europe and Japan based on the MONARCH 2 and the MONARCH 3 data, the single agent activity data will also be included in that package. And we have just recently announced that we both have got priority review for the MONARCH 3 so that's in combination with AI which means that the FDA is looking at an 8-month review versus the 12-month. And that's, as a reminder, based on the interim data from the MONARCH 3 so we hope to have final data on that either the end of this year or next year.

Philip Johnson

Thank you, Sue. Dave?

David A. Ricks

Chairman, CEO & President

Thanks, John for your question. If I have it correctly, what you're saying is, as we think about the whole sector through time across all therapeutic areas, how do we -- what underlying trends do we see that would affect the innovative pharma business, and how does that affect our thinking about growth? I don't

think we've ever been more bullish about the underlying science in the therapeutic areas we operate in. And that's good news for the pricing dynamics too. So just to put that together, where we see very competitive pricing dynamics are in relatively older categories with less differentiation and in more primary care versus specialty care. And the second one is really because primary care doctors are much more time pressured and working through and building [indiscernible] in your office to deal with the various formulary. For a broader set of products than a specialist, there's a challenge for primary care doctors, specialists have set that up and work through it. So the anecdote for this long term which affects our strategy -- I can't speak to the broader sector, but we see where the investment's flowing, I think it's consistent -- is to continue to focus on creating more and more differentiated assets at launch, bigger effect sizes, more difference versus standard of care. I think, we see example in our recent launches with Trulicity, with going to a weekly from a daily or Taltz by getting 40% complete clearance versus what TNFs can do which is similar in the mid-teens. That's the kind of medicines we need to be working on going forward. Those that make a profound change versus the standard of care. And then investing through the life cycle so that you don't find yourself less differentiated as competitors continue to launch. Those are 2 dynamics that affect our thinking about the business. And coupled with specialty care which is the underlying global trend that both the -- there's more innovative opportunities in areas like immunology and oncology relative to others -- areas of scientific inquiry, and that happens to correlate highly with where reimbursement can happen a little more easily because the hurdles that are produced by the payer system -- basically patients and providers are more willing to work through them for a more serious disease. And I'm not saying that's a great answer for humanity long term. I think, we need to find a way to pay for and fund innovation in conditions like diabetes and cardiovascular disease which are still some of the largest killers in the world. But that's just, I think, where both innovation's flowing in, where R&D dollars have. That affects our strategy and our thinking to continue to stay ahead of what will be a price effect due to competition. The ultimate antidote is differentiation. In terms of patient, you're asking a very important question. We're seeing in the U.S. this structural problem for many years of the pharmacy benefit having about 20% copay by patients out-of-pocket versus about 4%, 5% for services like hospital services. That really hasn't changed. What has changed is the number of patients who are exposed to very high deductible. So there's both a cash flow issue during the year as well as just overall out-of-pocket increases particularly for brand name drugs, generic prices remain relatively low and penetration relatively high. We think an immediate step that should be taken in all sectors, all segments is to pass through rebates to patients. This provides an immediate point-of-sale discount. I would share with you that, that is something commercial payers are now offering in the 2018 cycle. We, ourselves, as an employer are evaluating that. We think that's a great step to ease out-of-pocket burdens. We've advocated aggressively with CMS that, that should be policy at Part D, particularly for a donut hole, that's one solution to help seniors pay for the medications. And then I think, long term, we need to ask, I think, a broader question, which we can get at through value pricing mechanisms potentially, which is to really ask our medicines a better way to deliver health care than other parts of the health care system. And if so, why do we ask patients to pay more for it. And I think that's debate, a national debate, we need to continue to engage in. Again, I think we're making great strides scientifically, but the system isn't well equipped to help patients have affordable access to these inventions.

Philip Johnson

Thanks, Dave.

Operator

Greg Gilbert with Deutsche Bank.

Gregory B. Gilbert

Deutsche Bank AG, Research Division

With respect to animal health, Jeff, perhaps you can comment with more granularity on some of the revenue pressures you're seeing? And are they Elanco issues or industry issues? And where's your atopic dermatitis pipeline given the success of APOQUEL and CYTOPOINT? Interested to know when you could show up in that market. And then for Enrique, higher-level question beyond the sort of tit for tat on individual diabetes compounds. In the past when we've met, you've suggested that there could be more

of a push to partner with technology companies to enhance your overall diabetes franchise and solutions-based approach. So what can you say about that strategy at this point?

Philip Johnson

Greg, thank you for the questions. So, Jeff, commentary on the revenue pressures, what's Elanco versus industry in terms of dynamics? And a little bit the pipeline and outlook for getting into the atopic dermatitis, the companion animal space and then, Enrique, question over to you on our strategy for working with devices and device companies going forward. Jeff?

Jeffrey N. Simmons

Senior VP & President of Elanco Animal Health

Yes, Greg, real quick like on animal health. I think I would just come back on Elanco. Just kind of to anchor back, we again grew 4% excluding FX. We did see strong growth in global poultry. And I think that overall sector is growing well. We grew 17%. And then, of course, the U.S. companion animal vaccine. The pressures really remain and I'll kind of separate them. One is all around market access which is driven by the clean food kind of movement with antibiotics and productivity products. I think this is an industry issue depending on the product mix. And then any competitive pressures that are coming from a combination again in food animal that's a mix of economics of the industry as well as some generic pressure. So we saw that in U.S. cattle both with beef and dairy. The companion animal parasiticide space, let me just highlight, as Dave mentioned, Trifexis was an issue where we lost some share, no question. I think everyone has seen increased spending. Innovation is getting rewarded. So the new entrants have gained share. We still feel very good about companion animals and the parasiticide space in general given the size of our portfolio, existing portfolio and our heartworm platform as well as our pipeline. The market itself is still growing on the companion animal side and parasiticides, and then, I think lastly, is just the channel opportunities that are coming there. So again, I think you got some industry dynamics with cattle, beef and dairy. You've got some generic pressures a little bit there where there's lacking innovation on the food animal side, but overall, again, we see sectors like poultry, aqua and even companion animals growing in the vaccine space. I think relative to atopic dermatitis, we are actively exploring several mechanisms here related to symptom treatment as well as interruption of disease process for the canine atopic dermatitis area. We're leveraging Lilly's experience here. No question, we'll continue to advance novel product concepts. Both large molecule and small molecule are being studied here. So it's an active platform in our pipeline and we're focused on this.

Philip Johnson

Great, thanks, Jeff. Enrique?

Enrique A. Conterno

Senior VP & President of Lilly Diabetes

So we are, in fact, excited about the opportunity brought by the convergence of both pharmaceuticals and technology to be able to create differentiated solutions and to be able to provide [indiscernible] for an area like diabetes. We think that this could be pretty revolutionary. So that's something that we have a high interest on. I'm not prepared to share too much more than that but just to say that we are actively working on it.

Philip Johnson

Thanks, Enrique.

Operator

Steve Scala from Cowen.

Stephen Michael Scala

Cowen and Company, LLC, Research Division

On baricitinib, I have a follow-up to Shamus' question. So you stated that DVTs are in line with the expected background rate. Would you confirm that there has been no new imbalances even if they still remain within the expected background rate? And then on the second quarter call, Dr. Mahony said that KEYNOTE-189 top line release was not expected till late this year or early next. That was a surprising statement at the time given the September primary completion, but it has turned out to be correct. So I'm wondering if Dr. Mahony has any additional updates on the KEYNOTE-189 timing?

Philip Johnson

Great. Steve, thank you for the questions. Christi, question on DVTs, any new imbalances? And then Sue, any update on the KEYNOTE-189 readout timing? Christi?

Christi Shaw

Senior VP & President of Lilly Bio-Medicines

I can confirm there are no new imbalances in regards to DVTs.

Philip Johnson

Great. And Sue?

Susan M. Mahony

Former Senior VP & President of Lilly Oncology

And Steve, mine will be a quick answer too. I don't have any update. I think you need to go to [Merv] for any update on 189.

Operator

Vamil Divan from Credit Suisse.

Vamil Kishore Divan

Crédit Suisse AG, Research Division

One, I just wanted to ask a question about the guidance and more midterm guidance and you mentioned the 5% plus sales CAGR. And if you look at the models, I think our numbers, and also consensus in general is a little bit less than that. So as you review the models, are there certain products that you'd highlight where you think the extra sort of \$400 million or so in revenues may come by 2020 to get to that 5% number? And are there any expectations for business development that's built into that number? And then related to that, when would you think you're maybe comfortable giving us more guidance on 2020 in terms of OpEx or margins or maybe EPS growth or something along those lines?

Philip Johnson

Great. Vamil, thank you for the questions. Josh, we're going to road test you here. So if you'd like to comment a little bit, are there any BD transactions or placeholders built into that midterm guidance? And any kind of quantitative comments you can give around where The Street may be missing something and/or confidence in those numbers? And then we might give more details on 2020 or further out years in terms of midterm guidance.

Joshua L. Smiley

Senior VP & CFO

Sure, thanks. First, on the business development piece, we don't have future business development sales built into our projections around the 5%. As you know, we are very active in looking at external innovation and opportunities. So if we see those, those would obviously help or add to our projections. I think as it relates to the 5% goal itself, as Derica mentioned, we're very confident given the performance again this period was from 2015 to 2020. And when you look at how we performed since 2015 and where we are today, we think we've got really strong momentum to get us to the 5% CAGR through 2020. I think when we look at the models, we don't provide product level guidance, but I think our collective confidence is based on the strength of the new product portfolio. As we mentioned, they contribute 14

points of growth this quarter and you look across that portfolio of opportunities, Trulicity, Jardiance, Basaglar, Olumiant, Taltz, abemaciclib, et cetera. We think -- and with the pain portfolio coming, we see that portfolio continuing to grow and continuing to drive growth. So I think it's probably the collective performance of the new products that give us the confidence that we're well on our way toward that 5% target. I think as it relates to the OpEx guidance, we will provide 2018 guidance in December on our call, and you can expect us to provide some updates on how we see the remainder of the decade performing there. I think as Dave mentioned in an earlier answer, as it relates to our margin guidance, we've used 2018 just as a mile marker along the way toward being a more productive and expanded-margin company, and we'll look to provide some more color on that in our 2018 call this December.

Philip Johnson

Great, Josh. Thank you very much.

Operator

Geoff Meacham with Barclays.

Geoffrey Christopher Meacham

Barclays Bank PLC, Research Division

Just a couple of quick ones. On baricitinib, on the back of the recent data on atopic dermatitis, maybe just help us with the size and scope of the Phase III program that you're starting later this year and what you guys see as a biggest product differentiator? And on the RA side for Barry, should we expect any formal updates at medical meetings coming up, just on a broader safety question? And then last one on Alimta. I know overall demand trends have, in fact, been negatively impacted by -- but what are you guys seeing with respect to first-line lung trends just of late?

Philip Johnson

Great, Geoff, thanks for the question. So Christi, the first 2 to you for the size and scope of the Phase III program and potential areas for differentiation, any updates to the RA safety database coming in medical meetings. And then Sue, over to you for the trends in first-line -- non-small cell -- non-squamous non-small cell lung cancer for Alimta? Christi?

Christi Shaw

Senior VP & President of Lilly Bio-Medicines

So on the atopic dermatitis front, I think, just to clarify, we got a lot of questions on our Phase II data which I think is relevant for the question on what our Phase III study design looks like. So in our Phase II data readout, we're very pleased with the results. Unlike our competitors, one of the things that we looked at is what is the depth of efficacy that we could achieve and what I mean by that is we actually took the very resistant patient to corticosteroids. So we took patients. For 4 weeks, they were on the moderate dose of topical steroids. And those patients that responded were actually taken out of pre-randomization. So only those patients that were not responding to topical steroids were actually randomized to Phase III. And so you had, first of all, resistant patients to steroids, but second of all, you had patients that had less severe -- less disease severity. So the [EZ] scores at baseline were around 20, where you see our competitors who did the opposite used washout period of 4 weeks where patients will have an increased disease activity, their [EZ] scores actually started at 30 and 32. So that being able to show the results that we did in that patient population really gives us a lot of confidence as we move to the Phase III studies. And we will study Phase III similar to what our competitors did, now that we know the depth of the efficacies. So as we look at monotherapy, we look at various doses of the 1, 2 and 4 milligrams, we'll be looking at different dosing, the lower and higher. We are very confident that we'll have a robust study with robust results.

Geoffrey Christopher Meacham

Barclays Bank PLC, Research Division

And in terms of any updates from the RA program, safety updates coming at medical meetings, are there any -- my understanding was that BACE may have some repeats of things that were done earlier this year, but not necessarily new data.

Christi Shaw

Senior VP & President of Lilly Bio-Medicines

Correct. So we have a press release that will be coming out soon. We have 33 different scientific releases on both baricitinib and Taltz at ACR, and baricitinib will be new analysis that we have seen on safety, but no new surprises in a negative way. We look forward to showing you those and links to those will be within the press release.

Philip Johnson

Great. Thanks, Christi. Sue?

Susan M. Mahony

Former Senior VP & President of Lilly Oncology

Yes. Geoff, with regards to Alimta, as you mentioned, we have been challenged by IO uptake in the front-line setting over the past few months, and we've been seeing a sort of steady decline. We are pleased to see that we have seen a flattening in the front-line share. We now have a 26% share of market in front line. We've also seen an increase in the second line share, as IO's moved to front line and interestingly, as we're looking at the New to Brand, we're seeing an increase in the uptake of Alimta with Keytruda in the front-line setting.

Philip Johnson

Thank you for the update, Sue.

Operator

Richard Purkiss with Piper Jaffray.

Richard John Purkiss

Piper Jaffray Companies, Research Division

I have 2 questions for Enrique. Two quick ones. What proportion of patients initiating GLP-1 therapy in the U.S. now have some evidence of diabetic retinopathy? And then on average, in the U.S., how frequently are type 2 diabetic patients' retinas visualized?

David A. Ricks

Chairman, CEO & President

Enrique, I won't try to repeat. I think you heard those clearly. So we'll go to you for the answer.

Enrique A. Conterno

Senior VP & President of Lilly Diabetes

Not the second part.

David A. Ricks

Chairman, CEO & President

So the first one was a percent initiating GLP-1 that have evidence of retinopathy. And then the second one is the percent of patients -- diabetics in the U.S. that are actually being scanned currently to look for evidence of retinopathy.

Enrique A. Conterno

Senior VP & President of Lilly Diabetes

So excellent questions. Unfortunately, on the last question, not enough. There's really a nominal number of patients with diabetes that actually do get screening. When we look at the patient with diabetes -- I

don't have the specific numbers for GLP-1, but when we look generally for patients with diabetes, they're about 30% of patients with diabetes have some degree of retinopathy. If you were to look at the more serious retinopathy which is vision threatening, we're looking probably a number of 3% to 5%.

Philip Johnson

Great. Thank you, Enrique.

Operator

Jeff Holford with Jefferies.

Jeffrey Holford

Jefferies LLC, Research Division

Just want to dig a bit more into the JAK and [bari] safety. So can you just help us understand a bit better what the additional data and exposure data that you have will achieve do you think in light of the questions the FDA have around your original submission, because I think, as you referred to before, there was a cluster of events there and just how additional exposure data potentially changes that? Secondly, can you just tell us exactly what is the background rate data that you referred to in terms of what you think should be there in this population? Obviously, some of these clinical trial populations have different levels of cardiovascular risks. And I don't know if you've really talked to whether your view was that some of the trials you had are particularly high or relatively low cardiovascular risk. And then is there anything that you are doing differently in your Phase III atopic dermatitis trial in terms of crossover length of exposure? Just other things to help address this question a bit more robustly going forward.

Philip Johnson

Right, Christi, all those are for you. So the additional safety data, what we think it's going to achieve. What is that background rate that we're referring to in this population? What population is that? And then if there's anything we're doing with atopic dermatitis studies in Phase III that could help to shed light on this particularly safety issue as well?

Christi Shaw

Senior VP & President of Lilly Bio-Medicines

So in terms of what the additional data will help us with, let me start with the background rates, actually, if that's okay. Background rates in the rheumatoid arthritis patient population already are 0.3 to 0.8 per 100 patient years. So in the general rheumatoid arthritis patients, if they weren't on baricitinib, that would be the incidents that they report. And so when I say that our background rates are similar to that, our specific background rate during the development programs was 0.46 per 100 patient years. And so when I also say now, since we've submitted in the real-world evidence in atopic dermatitis and all of the data that we've accumulated, that background rate is still within the general rate of the rheumatoid arthritis development program -- or the background rate of the rheumatoid arthritis patient, excuse me. So that's what -- hopefully that clarifies it. Our background rate is similar to what you'd see without using baricitinib in this patient population. The additional data, I think, as we discussed with FDA, you have your clinical trial program, we submitted it in January '15. Since then, typically when the FDA looks at approving a drug, they say is it safe and is it effective. Or is it -- what is that balance. And now that we have real-world evidence, when they look at that, they're trying to protect patients. Now that we have patients actually in the real world on baricitinib, why that is important is they can actually see in the real world when you're using baricitinib, how does it really play out? And now that we've had over 5,000 patients with physicians using it in clinical practice, the way that someone normally would, not in a controlled environment, that we believe that, that gives even more confidence that our background rates matching rheumatoid arthritis in clinical trials as well as now in the new world -- in the real-world evidence is consistent. And then as we look at atopic dermatitis, I think the thing that this confirms is if you look at the patient population of patients who actually had a thromboembolic event, each one of those patients had a high risk for those before they had a thromboembolic event. So in the atopic dermatitis trials, we see a much younger patient population which is part of the reason we probably don't see any in

the -- through the Phase II trials we've seen so far and why we wouldn't anticipate seeing that many or a difference as we move forward with the Phase III trials.

Philip Johnson

Thank you, Christi.

Operator

Alex Arfaei from BMO Capital Markets.

Ardalan Arfaei

BMO Capital Markets Equity Research

Two questions, please, and a clarification. First, why did you discontinue the N3pG antibody in Alzheimer's? If I recall correctly, at your Alzheimer's R&D day, this was highlighted particularly given that it is similar to aducanumab. So what's incremental and new there that led to discontinuation? Second, on Elanco. Unless I'm mistaken, it's not growing organically excluding the BI vaccine acquisitions. So does it have enough of a pipeline in R&D productivity to sustain growth in line with the market? And then finally to clarify Humalog, did I hear you correctly that there are no legal barriers from your side preventing Sanofi from launching their biosimilars?

Philip Johnson

Thank you for the questions, Alex. So Jan, if you'll answer the question on the discontinuation of N3pG in the pipeline. Maybe Jeff and/or Dave, you want to comment on sort of what are the growth drivers going forward in pipeline prospects for Elanco? And then, Mike, if you want to clarify on the Humalog legal situation. Jan?

Jan M. Lundberg

Former Executive Vice President of Science & Technology

If we thought with plaque specific antibody N3PT, as you can see, on the pipeline chart, we actually have 3 molecules there for that target. And the front-runner molecule is still then inside the pipeline as active and the follow-on molecule did not meet the clinical criteria that we wanted. So, hence, we stopped it.

Unknown Executive

Just to be fair, we took a 2 to get 1 strategy in Phase I here. So [indiscernible] just playing all along.

Philip Johnson

And then Jeff, on the strength of the animal health pipeline?

Jeffrey N. Simmons

Senior VP & President of Elanco Animal Health

Yes, Alex, good question. Yes, we feel very good about our pipeline. Also, I think we launched a series of products last year and into this year that we're going to see growth on and then we'll talk more as we get near the end of the year in our guidance call and go into next year about additional launches. So it's not just a pipeline, but I think existing launches that are occurring now and ones that are right on top of us. And then I think the last thing is we're shifting our mix into these faster growing markets. So as I mentioned, the food animal vaccines, nutritional health, companion animals and aqua, as our mix gets higher in those spaces, that'll also drive more additional organic growth.

David A. Ricks

Chairman, CEO & President

Maybe if I could just add to that, just to be clear, we're not growing organically this year. The growth is the BI addition and companion and we described food animal pressures. I think we're not evaluating this business through the lens of 2017 performance. We're looking at the last 10 years, and we've built a globally competitive animal health company with a nice pipeline, with good opportunities to improve

margins and grow at pace and in some segments above industry pace. And as we look forward, and do this analysis, we'll be looking again at those long-term trends in animal health, and because we're broadly positioned across many of these segments and we do have innovation coming, we do expect forward trends to reflect those assumptions as we do the analysis. So this year, we've washed out some challenges. We've had some performance challenges. BI has helped us in terms of the stated growth rate, but we're looking at this decision making through a much broader lens of time.

Michael J. Harrington

Senior VP & General Counsel

Alex, you're correct. We have no legal basis to preclude Sanofi from entering the market. And as Enrique described earlier, we will compete with them in the marketplace.

Philip Johnson

That concludes the Q&A session. So David, if you'd like to wrap up the call please.

David A. Ricks

Chairman, CEO & President

Yes, I would. Again, I want to recognize and thank both Maria Crowe, who's been with us today and through many years as well as Derica Rice, at this last earnings call with us as CFO for a great performance through your careers and many contributions to our company. So thank you, again. We appreciate all of your participation on today's earnings call and your interest in our company. Through the last -- through the first 9 months of 2017, we generated solid revenue growth, driven by volume of our new pharmaceutical products, and we continue to improve margins. We're going to see even faster income growth. We believe Lilly remains a compelling investment given the strength of our product portfolio, our top and bottom line growth prospects over the balance of the decade. Please follow up with the IR team if we've not answered any questions on the call, or if you have follow-up questions. That concludes the call today. Have a great day.

Operator

Ladies and gentlemen, your conference will be available for replay beginning today, October 24, 2017, at 11:30 a.m. and lasting until October 24, 2018, at 11:59 p.m. To access the AT&T executive playback service during that time, please dial 1-800-475-6701. Internationally, area code 320 365-3844 and enter the access code 430109.

That will conclude your conference call for today. Thank you for your participation and for using AT&T's Executive Teleconference service. You may now disconnect.

Copyright © 2019 by S&P Global Market Intelligence, a division of S&P Global Inc. All rights reserved.

These materials have been prepared solely for information purposes based upon information generally available to the public and from sources believed to be reliable. No content (including index data, ratings, credit-related analyses and data, research, model, software or other application or output therefrom) or any part thereof (Content) may be modified, reverse engineered, reproduced or distributed in any form by any means, or stored in a database or retrieval system, without the prior written permission of S&P Global Market Intelligence or its affiliates (collectively, S&P Global). The Content shall not be used for any unlawful or unauthorized purposes. S&P Global and any third-party providers, (collectively S&P Global Parties) do not guarantee the accuracy, completeness, timeliness or availability of the Content. S&P Global Parties are not responsible for any errors or omissions, regardless of the cause, for the results obtained from the use of the Content. THE CONTENT IS PROVIDED ON "AS IS" BASIS. S&P GLOBAL PARTIES DISCLAIM ANY AND ALL EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE, FREEDOM FROM BUGS, SOFTWARE ERRORS OR DEFECTS, THAT THE CONTENT'S FUNCTIONING WILL BE UNINTERRUPTED OR THAT THE CONTENT WILL OPERATE WITH ANY SOFTWARE OR HARDWARE CONFIGURATION. In no event shall S&P Global Parties be liable to any party for any direct, indirect, incidental, exemplary, compensatory, punitive, special or consequential damages, costs, expenses, legal fees, or losses (including, without limitation, lost income or lost profits and opportunity costs or losses caused by negligence) in connection with any use of the Content even if advised of the possibility of such damages. S&P Global Market Intelligence's opinions, quotes and credit-related and other analyses are statements of opinion as of the date they are expressed and not statements of fact or recommendations to purchase, hold, or sell any securities or to make any investment decisions, and do not address the suitability of any security. S&P Global Market Intelligence may provide index data. Direct investment in an index is not possible. Exposure to an asset class represented by an index is available through investable instruments based on that index. S&P Global Market Intelligence assumes no obligation to update the Content following publication in any form or format. The Content should not be relied on and is not a substitute for the skill, judgment and experience of the user, its management, employees, advisors and/or clients when making investment and other business decisions. S&P Global Market Intelligence does not act as a fiduciary or an investment advisor except where registered as such. S&P Global keeps certain activities of its divisions separate from each other in order to preserve the independence and objectivity of their respective activities. As a result, certain divisions of S&P Global may have information that is not available to other S&P Global divisions. S&P Global has established policies and procedures to maintain the confidentiality of certain nonpublic information received in connection with each analytical process.

S&P Global may receive compensation for its ratings and certain analyses, normally from issuers or underwriters of securities or from obligors. S&P Global reserves the right to disseminate its opinions and analyses. S&P Global's public ratings and analyses are made available on its Web sites, www.standardandpoors.com (free of charge), and www.ratingsdirect.com and www.globalcreditportal.com (subscription), and may be distributed through other means, including via S&P Global publications and third-party redistributors. Additional information about our ratings fees is available at www.standardandpoors.com/usratingsfees.

© 2019 S&P Global Market Intelligence.