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EPS of \$1.05 beats by \$0.21 | Revenue of \$2.12B (-1.94% Y/Y) beats by \$41.13M

Bausch Health Companies, Inc. (NYSE:[BHC](#)) Q4 2018 Earnings Conference Call February 20, 2019 8:00 AM ET

Company Participants

- Arthur Shannon - SVP and Head, IR & Communications
- Joseph Papa - CEO & Chairman
- Paul Herendeen - EVP & CFO

Conference Call Participants

Umer Raffat - Evercore ISI
David Risinger - Morgan Stanley
Christopher Schott - JPMorgan Chase & Co.
Irina Koffler - Mizuho Securities
David Ansellem - Piper Jaffray Companies
David Steinberg - Jefferies
Louise Chen - Cantor Fitzgerald & Co.

Operator

Good morning, and welcome to the Bausch Health Care Fourth Quarter 2018 Earnings Conference Call. [Operator Instructions]. Please note, today's event is being recorded. I would now like to turn the conference over to Art Shannon, Senior Vice President of Investor Relations and Communications. Please go ahead, sir.

Arthur Shannon

Thank you, Rocco. Good morning, everyone, and welcome to our Fourth Quarter and Full Year 2018 Financial Results Conference Call. Participating on today's call are Chairman and Chief Executive Officer, Mr. Joe Papa; and Chief Financial Officer, Mr. Paul Herendeen. In addition to this live webcast, a copy of today's slide presentation and a replay of this conference call will be available on our website under the Investor Relations section.

Before we begin, we'd like to remind you that our presentation today contains forward-looking information. We would ask that you take a moment to read the forward-looking statement legend at the beginning of our presentation as it contains important information. This presentation contains non-GAAP financial measures. For more information about these measures, please refer to Slide 2 of the presentation. Non-GAAP reconciliations can be found in the appendix of the presentation posted on our website.

Finally, the financial guidance in this presentation is effective as of today only. It is our policy to generally not update guidance until the following quarter and not to update or affirm guidance other than through broadly disseminated public disclosure. And with that, it is my pleasure to turn the call over to Joe.

Joseph Papa

Thank you, Art, and thanks, everyone on the phone for joining us today. Let's quickly review the topics we will cover. I'll begin with a brief summary of our 2018 company highlights before turning the call over to Paul Herendeen, our CFO. Paul will take us through the fourth quarter and the full year financial results and provide our 2019 guidance.

I will then review the segment highlights and catalyst before opening the line for questions. Beginning on Slide 4, 2018 was a year of strong execution for Bausch Health. For the full year, the total company grew organically by 2%. This was the first year of total company organic revenue growth since 2015. We also generated organic revenue growth in all 4 quarters of 2018. Now international and Salix, our 2 largest segments grew organically by 6% on a combined basis during 2018.

Our top 10 products grew organically by 11% in the aggregate compared to 2017. We generated \$1.5 billion of cash from operations. We increased R&D investment by more than 30% in the fourth quarter and approximately 15% for the full year. And we improved our gross margin through manufacturing efficiencies both in the fourth quarter and the full year. And we resolved the XIFAXAN IP litigation, which we believe preserves the products market exclusivity until 2028.

Moving to the top right, we launched 10 key products during 2018, including two copromotions, 4 of our Significant Seven products were launched during the year, and we are expecting a decision from the FDA on DUOBRII shortly. We'll also continue to delever our balance sheet, having repaid more than \$1 billion of debt in 2018 and cash generated from operations.

Finally, in 2018, we refinanced approximately \$8.3 billion of debt to extend maturities and provide more flexibility, which gives us the ability to pivot to offense in 2019.

Turning to Slide 5. We have a snapshot of the key 2018 financial highlights for each of the 4 segments. Approximately 75% of our total 2018 revenue was generated by the B + L/International segment and the Salix segment combined. B + L/International grew organically by 4% compared to 2017 with organic growth across all 5 reporting businesses. Salix grew by 12% organically in 2018, driven by XIFAXAN, which had a great year with 22% growth. Great results from our two largest segments. Delivering on commitments is important to us.

On Slide 6, we show how we perform against the guidance we provided 1 year ago, in February 2018. A year ago, we promised to deliver 2018 revenues in the range of \$8.1 billion to \$8.3 billion. We actually delivered \$8.38 billion. A year ago, we promised to deliver adjusted EBITDA in the range of \$3.05 billion to \$3.2 billion. We delivered \$3.47 billion. Paul will walk you through the fourth quarter and the full year results in more detail. So with that, I'll turn it over to Paul.

Paul Herendeen

Thank you, Joe, I'm going to start on Slide 7, the top level financial results for the quarter. Before I begin, I want to point out that when we talk about organic growth that means on a constant-currency basis and removing the impact of divestitures and discontinuations in the comparative period. One other note, on the Q3 call, I referenced our initiative to reduce the level of channel inventories of our branded U.S. pharma products that would have the effect of reducing our revenues in Q4 and for the full year 2018 by an estimated \$100 million. As it turned out, the actual result was a \$76 million drag on revenue that was spread across all 4 of our segments. I'm going to reference this item a lot, and we've included a slide in the appendix that shows the impact on revenue and profit by segment.

Okay. Let's go. We had a very strong finish to 2018. We posted our fourth consecutive quarter of organic growth despite the completed channel inventory reduction. Q4 revenue was up 1% organically and would have been up 5%, but for the channel inventory reduction, a good stuff. The B + L segment comprising 57% of our revenue was up 5% organically, with 4 of the 5 businesses within that segment delivering organic growth. Salix was up 1% organically despite the dramatic impact of the channel inventory reduction on the Salix segment. Ortho Derm was down 2% and Diversified was down 9% organically. Stepping down to gross profit and gross margin, we post a 150 basis point improvement in gross margin. A good chunk of the improvement was due to mix, but we also realized a meaningful improvement in our supply chain efficiency, driven by the ongoing efforts of Dennis Asharin, our Head of Global Manufacturing and his team. Over the last couple of years, the manufacturing team working together with Dr. Louis Yu and our quality organization, have been implementing a right first-time ethos that has decreased costs and reduced supply chain disruptions. Down in operating expenses, if you look at the reported selling, advertising and promotion line, it looks like we reduced those expenses by 4%. But adjusting for currency and divested businesses in the prior year, we actually spent more on our go-forward business in Q4 of '18 versus '17, mainly additional sales resources and promotional dollars to drive longer-term growth. This will be a theme for us in 2019, and that's why I'm framing it for you here.

G&A was flat on a constant-currency basis and reflects our ongoing efforts to control costs that don't directly drive revenue. Investment in R&D meanwhile, was up \$30 million compared with Q4 of '17. Consistent and increase investment in R&D is a significant part of the ongoing transformation of our company and is integral to our ability to drive long-term organic growth across our core businesses. At the operating profit lines, adjusted EBITA and adjusted EBITDA, we were basically flat organically versus the prior year quarter. Pretty impressive if you think about the \$30 million year-over-year increase investment in R&D and the \$65 million negative impact of a channel inventory reduction. The low operating profit, net interest expense was down versus Q4 of '17 by \$33 million and our tax rate on adjusted earnings was 3.2% versus 5.8% in the prior year. Those items account for our Q4 adjusted net income growing at a faster pace than operating earnings. As I said earlier, a good strong finish to 2018.

As I go through the 4 segments, I'm going to focus mainly on revenue. Starting on Slide 8, with B + L/International. Really good quarter, 4 of the 5 businesses delivered organic growth and the one that didn't, Global Ophtho Rx would have grown 5%, if not for the channel inventory reduction. From a growth perspective, Global Vision Care was the star, up 12% organically led by the U.S. business that was up 23%, driven by the impact of increased promotional resources we deployed beginning back in 2017 and the successful launch of expanded parameters of Biotrue ONEday toric. International Vision Care also delivered strong growth, up 8%, driven by strength in SofLens daily disposables, ultra-monthly SPS and cosmetic lenses. Geographically, International Vision Care was up 11% organically in China and 9% organically in Japan.

Global Surgical was up 4% organically, up 6% outside the United States and plus 1% in the U.S. A quick comment here. The international surgical business representing roughly 70% of Global Surgical has delivered consistent organic growth over the last 7 to 8 quarters, while the U.S. surgical business only recently returned to growth in the second half of 2018. As the U.S. part of the business continues to deliver more consistent results, the Global Surgical business can deliver better growth that we've observed over the last 2 years.

The Global Consumer business was up 4% organically, led by the U.S., that was up 8% on strength in our eye vitamins and the successful launch of LUMIFY. Outside the United States, consumer was up 1% as strength in our Latam cluster from new product launches was partly offset by lower demand for our topical products in the Russia. The Global Ophtho Rx business declined 1% organically on a 4% volume decline, driven entirely by the channel inventory reduction in the U.S. The Global Ophtho Rx business would have grown 5% versus Q4 of '17, but for that channel inventory reduction and that growth would have been basically split between increased volume and increased net realized selling prices. International Pharma, which is our branded generics business in Eastern Europe, Russia, Canada, Africa, Middle East and Latam rebounded after 4 quarters of subpar performance.

You may recall that I previously called out some of the challenges we faced in our Eastern European Russian cluster and that I suggest that we would start to see improvement there based on changes we made in organization and leadership. While it's too soon to declare victory, our Russian business turned around from being a growth drag earlier in the year to being a significant contributor to the 8% organic growth of this business in Q4. A quick tip of the hat to John Connolly and Vladimir Gudkov for their efforts. Meanwhile, in Africa, Middle East that cluster continues to deliver strong growth led by Amoun, which was up 25% organically for the quarter and 19% for the full year.

We have a great team at Amoun, and we look forward to seeing that team leverage its competitive strengths to drive increased business not only in Egypt but ultimately, in other Middle Eastern markets. On to Slide 9, in Salix. Salix took the brunt of the impact of the planned channel inventory reduction, \$47 million and absorbed the impact of the mid-year loss of the exclusivity of UCERIS and still delivered 1% organic growth. Excluding the channel inventory reduction, Salix would have grown 12% versus Q4 '17, driven by XIFAXAN where TRxs were up 8% in the quarter versus the prior year quarter. The nidus of Salix performance is the team, including Mark McKenna, Nicola Kayel and Josh Coyle. They have performed at a very high level. Note that the Salix segment was one of the major beneficiaries of our improved gross profit margin, up some 290 basis points versus Q4 '17, due to mix and manufacturing efficiencies.

On to Slide 10, in the Ortho Dermatologics segment. The segment was down 2% organically, as spectacular growth in Global Solta was more than offset by an 11% decline in the medical dermatology business. Solta was up 32%, driven mainly by the successful rollout of Thermage FLX, but also basic better fundamental performance across many of our regions under the terrific leadership of Tom Hart in his canorous Aussie accent. To wrap up the Q4 segment discussion, turn to Slide 11 in the Diversified Products. The segment was down 9% organically. Absent the channel inventory reduction, Diversified would have been down a rather modest 5% organically. Pretty good when considering the \$41 million drag from the LOE products versus Q4 of '17 fell in the neuro segment there -- business there. Our generics business was a star performer based on 2 factors. First, the launch of authorized generics for our branded products that lost exclusivity. In Q4 '18 versus Q4 '17, the big contributors were UCERIS AG and Elidel AG. And second, the generics team led by Mary Saharyan worked closely with our supply chain to capitalize on market opportunities across our generics portfolio, not just in the quarter, but throughout the year. The generics business was up 18% versus Q4 '17 mostly on volume, but we were able to get some positive contribution from price too, a really good job.

Flip to the full year 2018 versus '17 on Slide 12. The themes are similar to what we saw in Q4. Revenue was up 2% on an organic basis and would have been up 3%, but for the \$76 million impact of the completed channel inventory reduction. Salix led the way from a growth perspective, up 12% would have been 15%, if not for the channel inventory reduction. We posted really strong growth with XIFAXAN, APRISO and the RELISTOR franchise that was slightly offset by the impact of the July LOE for UCERIS. B + L/International was up 4% organically versus 2017 with all 5 businesses delivering organic growth. The Ortho Dermatologics segment was down 13%, as Global Solta's plus 22% growth versus the prior year was more than offset by the continued rebasing of the medical dermatology business.

Finally, Diversified posted a 5% organic decline, modest compared with the 24% decline we saw in 2017 as the growth drag of the LOE assets moderated in 2018 and was offset in part by the solid 19% growth in the generics business. Note the gross margin improvement versus 2017 roughly 110 basis points, same things as we saw in Q4, mix and supply chain efficiency.

We reduced G&A by some 6% on a constant-currency basis, partly on reduced legal expenses. Finally, we increased our investment in R&D by some 15%, with the expectation that we'll continue to invest more in R&D in 2019 versus '18. Adjusted EBITDA was up 3% organically to \$3.474 billion despite the \$65 million drag of the completed channel inventory reduction. Pretty good, right? Adjusted net income grew faster organically than adjusted EBITDA as our net interest expense decreased \$154 million compared with 2017, due to our successful and continuing efforts to reduce debt. And we saw a decrease in our tax rate on adjusted pretax earnings from 13.2% in 2017 to 8.4% in 2018.

Turning to the balance sheet summary slide on Slide 13. You see the progression of our debt balance since last year. Debt is down \$1.12 billion from the end of 2017. We ended the year with \$24.6 billion of debt, \$723 million of cash and a modest \$75 million outstanding under our revolving credit facility. After year-end, we did prepay another \$100 million of debt. On to Slide 14, in our cash flow summary. Cash provided by operating activities for the full year totaled \$1.501 billion. In the first half of the year, the settlement of several legacy legal cases reduced that amount by roughly \$225 million. So for the year, our cash provided by operating activities was in line with our expectations.

Sequentially, our cash provided by operating activities went from \$522 million in Q3 to \$319 million in Q4. Note that as a result of refinancing debt, roughly 1/3 of our cash interest is now paid in each of Q2 and Q4. Looking backward, the settlement of interest had been relatively consistent across the 4 quarters. This change had a meaningful impact on the phasing of cash generated by operating activities in Q4 versus Q3 and that will continue in the future. Shifting to our guidance for 2019. The particulars of our guidance are spelled out on Slide 15. The highlights, we're expecting revenue in the range of \$8.3 billion to \$8.5 million and adjusted EBITDA in the range of \$3.35 billion to \$3.50 billion. Our guidance implies organic revenue growth in the range of flat to plus 3% and organic growth of adjusted EBITDA from minus 2% to plus 2% when compared with 2018. There's a bridge from 2018 actuals to our guidance on Slide 16.

The very strong finish to 2018 took a bit of a top off of our growth expectations for 2018, but we'll take the good performance that we put on the board and move forward. And adjusted EBITDA, when looking at 2019 versus 2018, bear in mind that our guidance contemplates an approximately 10% of \$40 million increase in investment in R&D and meaningful increases in selling and promotional expenses to support our recently launched and to be launched brands. If we were managing solely to deliver near-term growth of adjusted EBITDA, I have no doubt that we could put a higher EBITDA range on the board for 2019. But we're playing the longer game, and that means sacrificing a bit of near-term profits to deliver a better, more valuable future.

I want to call your attention to some of the guidance details included on the slide. You see that we expect to increase CapEx in 2019. This is mainly growth CapEx for our initiative to introduce new daily silicone hydrogel lenses, but also to fund the overdue build out of our global IT infrastructure. We've also added a few new line items to our guidance slide, namely our expected gross profit margin, which we expect to be in the range of 71% to 72% in 2019 and our expected full year cash generated from operations, which we expect to be in the range of \$1.5 billion to \$1.6 billion. Note that our reported gross margin is sensitive to changes in FX rates, so please bear that in mind. Finally, we believe that on a constant-currency basis and for the midpoints of our 2019 guidance, we can grow over the next three years to 2022 at compound annual growth rates of between 4% to 6% for revenue and 5% to 8% for adjusted EBITDA. That's it for me, Joe.

Joseph Papa

Thank you, Paul. Moving now to Page 17, our Bausch + Lomb business is a fully integrated eye health business with offerings across the spectrum of vision care, which include contact lenses, surgical, consumer products and prescription ophthalmology. Importantly, this integrated business is being driven by several global megatrends that we see creating increased demand for our eye health products. First, recent statistics indicate that there are approximately 1.3 billion people in the world who live with some kind of vision impairment and 80% of all vision impairment is generally considered to be avoidable. Another megatrend is the graying of the United States population as the baby boomers hit age 65 and above. People over the age of 65 use 8x as many eye care products than those under the age of 65. Clearly, an important megatrend. In addition, the prevalence of myopia or nearsightedness is increasing to epidemic levels. As the graph shows, myopia rates in Hong Kong are steadily increasing. About 30% of those born before 1950 to a staggering 87% of those born in the last 20-or-so years. This data suggests that environmental factors like increased screen time with laptops, cellphones are responsible for the high rates of myopia we are seeing in Hong Kong and in other parts of the world.

Myopia statistics are important to our business for obvious reasons, but also because myopia is a risk factor for glaucoma, macular degeneration and retinal detachment. Based on these megatrends, we are projecting growing demand for eye care, and we believe Bausch & Lomb as a global integrated eye health business is well positioned to provide them.

On Slide 18, the B&L segment delivered its ninth consecutive quarter of organic growth, generating 2 years of mid-single-digit growth organically. E-commerce sales through Amazon grew by 64% in 2018 versus 2017. And we saw a 44% spike in sales at a B&L flagship store and Alibaba Singles' Day during the fourth quarter. The performance of our Global Vision Care has been phenomenal, driven by Biotrue ONEday and Bausch + Lomb ULTRA, the U.S. business significantly outperformed the market, up 13% versus 2019 compared to 4% to 5% growth for the rest of the industry.

Moving now to Global Consumer, LUMIFY, which was launched in May is now the #1 product in the Redness Reliever category with approximately 28% market share. LUMIFY is also #1 product recommended by optometrists and ophthalmologists for redness relief. The B + L eye vitamins, PreserVision and Ocuvite grew organically by 7% in 2018 on a combined basis.

Finally, in global ophthalmology, VYZULTA TRx weekly prescriptions grew by more than 50% sequentially in the fourth quarter of 2018 versus the third quarter 2018. Also, we know the data tells us that patient start on VYZULTA are 34% more likely to stay on it than other branded agents, which brings us to market access, where our position has substantially improved versus earlier in 2018. We are now up to 80% commercial coverage and Part D coverage is up to about 30%. However, more than half of the Part D prescriptions are being covered today. We are making good progress here.

Finally, VYZULTA was approved to the second market, Canada last month. So we believe the product has good momentum and a lot of opportunity ahead. Over to Slide 19, I want to emphasize the strengths of our international business which ties into the megatrends I mentioned earlier. As you can see from the map, our branded franchises have market-leading positions throughout Canada, Latin America, Europe, Middle East, Africa and importantly, Asia. Bausch + Lomb Vision Care is the leader in key emerging markets like China, Thailand and India, which represent approximately 40% of the world's population and are among the fastest-growing markets. The key takeaways I want to emphasize that approximately 58% of our business is not currently exposed to U.S.-branded prescription pricing.

Turning now to Slide 20, we've given a sense of the near-term product pipeline across the entire eye health business. I'll summarize by saying that Bausch & Lomb is a diversified and fully integrated eye care business, our integrated eye -- our integrated platform is a significant strength for us, particularly given the trends that we expect to drive global eye care consumption. And as you can see from this slide, we have a number of great opportunities in our pipeline that we believe will enable us to grow at mid-single-digit growth rate.

Moving now to Salix highlights on Slide 21. Let's start with XIFAXAN. I want to provide perspective on the reported 2018 revenue growth of 22%, which is 1/3 of the volume came from strong TRx gains, volume gains. 1/3 from our Project CORE activities that improved gross to net with better co-pays, couponing and rebates. And about 1/3 falls in the category of gross pricing improvements. We think, though that we are just scratching the surface at XIFAXAN when you consider that chart on the right, which shows that 90% of the IBS-D market is still being treated by antispasmodic or antidiarrheals. In other words, 90% of the market represents a significant growth opportunity for XIFAXAN in IBS-D. Finally, we expanded our GI business by obtaining rights to other copromote products. LUCEMYRA, DOPTELET and PLENVU complement our existing products, and we expect these additional offerings to help drive revenue growth.

Let's move on to Slide 22 and talk about the Salix pipeline. We're continuing our R&D investment in rifaximin by developing a number of new formulations and importantly, new indications that we listed on the chart. We have great opportunities with XIFAXAN. We also have a potential bolt-on acquisition opportunity that we are excited about. We entered into a stalking horse agreement to acquire certain assets of Synergy Pharmaceuticals, TRULANCE for chronic constipation in IBS-C and also an investigational compound, dolcanatide, which has demonstrated proof of concept in treating patients with multiple GI conditions.

We think these assets are a natural fit to what we are already doing gastroenterology and primary care. And we have some capabilities in terms of scale, supply chain and managed care expertise that can help improve the performance of TRULANCE. If we are successful, we expect the transaction to close in March of 2019.

Moving on to Slide 23, Ortho Dermatologics. While this segment has trailed B + L/International Salix turnaround, the business continues to stabilize as we launch new products. SILIQ generated \$6 million of sales in the fourth quarter and as you can see from the chart on the right, TRx weekly scripts grew more than 30%, TRx growth in fourth quarter 2018 versus the prior quarter.

We also launched two products -- new products during the fourth quarter, ALTRENO, an innovative new retinoid acne treatment and BRYHALI, a new potent steroid treatment for plaque psoriasis. Our aesthetics business, Global Solta was a bright spot driven by strong -- by the strength in the U.S., Korea and Taiwan and the expected global launch of Thermage FLX. We also have announced a transformational new model for our dermatology products in the U.S. that we believe will give us an opportunity to grow the overall business. The business will pursue two separate access models. Reimbursed medical dermatology, which is a continuation of our current model and cash pay prescription dermatology.

In light of the challenging payer environment for dermatology products, we believe this new cash pay prescription model offers improved, predictable and sustainable fulfillment options. For example, with our new model, adult women prefer our cosmetic elegant formulation of 0.05% tretinoin lotion will now be able to get ALTRENO from their dermatologists at a predictable price, which pushed the treatment decision in the hands of the doctors and the patients.

On Slide 24, I want to talk about DUOBRII, which upon approval expected to be the first and only topical lotion that contains a unique combination of halobetasol and tazarotene in one formulation for the treatment of plaque psoriasis. We announced on Friday that the FDA is close to finalizing its review, and we expect a decision from the FDA shortly. We remain optimistic about this opportunity. First, there are about 7.5 million psoriasis patients in the United States and between 150,000 to 260,000 new cases diagnosed each year. Second, research shows that 90% of patients with psoriasis are open to new treatments and third, 85% of the patients on therapy use a topical medication. Our actuarial model suggests that by using DUOBRII, even a small reduction in the number of psoriasis patients that need a biological treatment could result in a fairly large net savings for health plans.

On Slide 25, we show the anticipated revenue growth of our Significant Seven products, 6 of which have been launched today. As the blue bar shows, this group of products represented approximately \$75 million of revenue in 2017 and that doubled in 2018 to more than \$150 million. We are projecting another double in 2019 to approximately \$300 million, with expected peak annualized total revenues of over \$1 billion by the end of 2022. We're excited by what this means in terms of being able to launch new products that make a difference in patients lives.

Finally, Slide 26 sets out our expectations for 2019, a year of growth for Bausch Health as we pivot to offense. First and foremost, we expect reported revenue for the total company to grow in 2019 versus 2018 at or above the midpoint of our guidance range in the current FX rate.

Second, cash generation. We expect to generate \$1.5 billion to \$1.6 billion of cash from operations, and we plan to use more than \$1 billion of that cash opportunistically to reduce debt and/or for bolt-on acquisitions. R&D investment is expected to increase by about 10% in 2019 as we continue to develop innovative products that improve patient lives. Revenue generated from our Significant Seven products is expected to double in 2019 to approximately \$300 million.

Our continued efforts to improve operational efficiency, which we refer to internally as Project CORE are expected to deliver more than \$75 million in operating profit in 2019.

And finally, we're meeting expectations on our previous growth guidance and adding that Bausch Health expects a 3-year compound annual growth rate from the midpoint of our 2019 guidance of 4% to 6% revenue growth and 5% to 8% adjusted EBITDA growth during the period from 2019 to 2022 on a constant-currency basis.

Based on our 2018 results and our outlook for 2019, we believe that Bausch Health is well positioned to continue the momentum that is driving the company's transformation as we now pivot to offense. With that, operator, let me open up the line for questions.

Question-and-Answer Session

Operator

[Operator Instructions]. Today's first question comes from Umer Raffat of Evercore ISI.

Umer Raffat

I wanted to touch upon two topics. First, as we head into 2019, can you -- perhaps this ones for Paul. Paul, can you lay out for us some of the comments you shared at the conference in January, where you talked about growth and the real growth CAGRs relative to the roughly flattish guidance? And could you also give us a sense for the amount of growth to net improvement impact that you expect in 2019? And then my second question is, perhaps for Joe. Joe, I know there's like this 300-plus patient trial for XIFAXAN SSD formulation, potentially due at some point this year. Could you walk us through the timing on that? And perhaps more importantly, how meaningful is that indication because it's my understanding that it's an acute indication, which only requires a couple of days worth of administration. So is that a trial and/or an indication that's commercially meaningful?

Joseph Papa

Okay. So Paul, why don't you start with that 2019 question and some of the growth and -- hand it back.

Paul Herendeen

Sure. And thanks for the questions, Umer. First of all, on the three year growth rate, I think, you characterized, our guidance is flattish. I mean, I referenced in my remarks it's a challenge for us relative to 2019, as we finished the year really, really strong, which we're happy about. So kind of took a little bit of the top off what you see for '19, but what we essentially done is reupped our 3-year CAGR guidance to say 4% to 6% for revenue, 5% to 8% for adjusted EBITDA, the midpoint of our 2019 guidance. There are included in our deck here, a lot of charts and bridges that point out that FX has been a challenge for us that people looking, oh, where are you relative to that? I say we're -- yes, we feel like we are continuing to be on track with our longer-range expectations for growth of both revenue and profitability. The big issue for us in 2019, we expect the profitability, I called out.

We're investing more in our business. And so you're not seeing that -- see -- you won't see 2019 wherever we end up with respect to revenue. That to translate directly to adjusted EBITDA growth because the increased investment in R&D and the necessary investments behind selling and promotional expenses for our launched and to be launched products. So we feel pretty good about our prospects for delivering growth over the course of the next several years. Your second question was -- I think was around gross to nets and what you can expect. I'd say that we had a very strong year with respect to gross to nets improving that. And I think we called it out on our last call and even at the beginning of the year, we had some things that we were able to successfully change in the nonretail channel. We had a couple -- I am looking to make sure I get it right. About a 200 basis point improvement, if you looked across the company for gross to net in 2018 via 2017. As we look ahead to 2019 via '18, we expect -- we would not expect that level of improvement. But we would expect to continue to improve our gross to nets across our portfolio in '19 via '18. Does that answer, Umer?

Joseph Papa

On the second part of your question, you asking us about the ongoing trial that we have in overt hepatic encephalopathy. A couple of things, I'll say. Number one, there are about 156,000 patients that are hospitalized because of hepatic encephalopathy. Obviously, anything we can do to reduce the hospitalization time or let's just say in the hospital as well as rehospitalization is an important question for us that we're looking at in that trial because we obviously think that's an important part of any pharmacoeconomic model and showing the value of our product. But importantly, there's a second reason for this trial. As you probably noted in the data that we're using our SSD formulation there. We expect that, that trial will give us some information on the use of SSD formulation and potential dose response, which can then help us with some of the later trials that we also believe are the larger opportunity. So it's important for our pharmacoeconomics to summarize and then also, it's important because it will give us a dose range and information that will help us as we look at some of the larger trials, for example, the prevention of the complication of decompensated psoriasis as an example, with other indications and other things we're going to look at with either the XIFAXAN 550 or the SSD formulation. So important to us for the near-term pharmacoeconomic and also long term.

Operator

And our next question today comes from Dave Risinger of Morgan Stanley.

David Risinger

So I guess, I wanted to start with LUMIFY. Could you just talk about that ramp and I know that the TV ad was well received. Do you plan to run that more frequently in 2019 to drive greater adoption? Second question is, with respect to the February 25 Lotemax franchise line extension PDUFA, should we expect an on-time approval? Or could that potentially be delayed due to the FDA backlog as a result of the government shutdown this winter? And then finally, just on contact lenses, could you please talk about the potential timing for additional SiHy launches globally?

Joseph Papa

Sure. Let me start, on the LUMIFY, we are delighted what we're seeing. As we mentioned in the call that we're now up to approximately a 28% weekly share in the latest data that we've seen just -- since we've launched this product just in May, we're really excited about it. We are back with TV advertising, as you -- now as you speak. We think that's an important part of it, but we also think the other part of it is the integrated eye care approach we have allows our teams in ophthalmologist offices and optometry offices to drop off samples and that's the reason we are getting great referrals and why we're the #1 referral product for the treatment of redness relief from ophthalmologists and optometry. So we think it's the integrated approach that really is helping us with what we're doing and making LUMIFY a better product. And of course, the other important reason I must add is that we believe we've got a better mechanism of action. We do not constrict the arterial blood flow to the eye. We constrict the venous blood flow, which we think is a much better way than approach on the redness relief category.

On the question, second question of Lotemax, the 0.38, you're absolutely, correct. We have a late February date for the PDUFA. At this time, I really don't want to speculate as to where the FDA is in terms of approving this product. We're obviously putting together all the information, and we put together that information. We believe we know the FDA is making good progress on it, but I don't want to really speculate as to exact timing what the date is. The PDUFA date is the date, but obviously, we know that the FDA in the case of DUOBRII was not able to complete their PDUFA date filing review on time. So I'm not going to speculate on what's going to happen on the, I think, it's February 25 date. Final comment, contact lenses, as you noted, we did launch the silicone hydrogel in Japan, and we've got plans to roll that out globally. That global rollout will be predominantly -- for example, the U.S. will be sometime in 2020 in terms of our launch plans for the silicone hydrogel launch here in United States.

Paul Herendeen

I'm going to just finish up on that because I think the U.S. market depending on the data set, uses approximately 40% of the global lens market, and so it's obviously a big target for us. The U.S. is also a market where more of the lenses are, I think, only -- I'd say, only about 45% of the U.S. market is in daily lenses now, which is low relative to the rest of the world. So we want to be in daily lenses in a daily SiHy because that is a fast growing and expected to continue to be a fast-growing segment of the market.

Operator

Our next question comes from Chris Schott of JPMorgan.

Christopher Schott

Just two questions here. Maybe first on XIFAXAN and just elaborating a little bit more on the 2019 outlook. Do you see more growth and improvements this year or should we be thinking about 2019 more as a year, where its volume and gross price increases driving growth there? So in '18 that was a big component of growth, and I'm just trying to -- and then talking about the whole business, but XIFAXAN specifically in '19, will that be a component of growth? My second question was on organic delevering. You're allocating more capital to the yields. You're also pivoting to offense a bit here. I guess, can you elaborate just to how you're balancing acquisitions relative to the debt payoff in the story, I guess, in general, should we still think about most of your cash flow being allocated to debt payoff at this point with some smaller deals mixed in or could these transactions actually account for more meaningful piece of your cash flow on a go-forward basis?

Joseph Papa

Sure, good questions. I think the XIFAXAN question and then Paul will comment about the organic delevering. On the XIFAXAN, we're really excited by what we're seeing. If I just look at what's happening so far in the 2019 time frame, we're seeing somewhere in the -- for example, in the month of January, XIFAXAN total prescriptions are up approximately 10%. So very strong growth in XIFAXAN volume. But we are projecting though as we think about is the combination in 2019 will be a combination of what we're seeing on prescription growth, call it high single digits there and then call it some net price improvements, which is a combination of gross price and also some gross to net things that we are doing. So I think, it's really a combination that we think can get XIFAXAN certainly to high single digit, low double digits in terms of the growth rate that we are projecting for XIFAXAN. So we're very excited. But one final comment I will say that some of you don't see, but we're also seeing very strong nonretail growth with XIFAXAN. That's the nonretail category, thinking of nursing homes, convalescent homes, hospital institutions, et cetera, where we're seeing actually they're also double-digit growth and that's another big driver, especially in the area of hepatic encephalopathy. So those have been the primary growth factors for XIFAXAN in 2019. Paul, do you want to take the question on the delevering in the debt?

Paul Herendeen

I do, but I want to chime in on the gross net on XIFAXAN because there's -- as financial analyst and I know each one on the phones is financial analyst. It's important, I mean, remember that back in -- when we reported our Q1, we talked about a pretty substantial improvement in gross to net from better pricing in that nonretail channel, Joe just referenced, which is growing quite nicely. We're going to lap that. So that had been kind of a step function, it had been a nice tailwind for us in Q1, Q2, Q3, Q4, for the full year. We're going to lap that, and it's a good thing. I mean, it's all good, but I think, looking ahead to 2019 via '18, Joe said exactly right. It's like we expect something on a unit basis and high single digits and price whatever gross selling price increase we take, we don't obviously expect to net that and realize all of that, but the 2 drivers next year will be -- next year versus '18 will be volume and whatever we can net out of price increases that we take.

With respect to the question around how do we expect to deploy our cash flow, Joe finished up with a slide that said, we have a \$1 billion to be used for debt and/or bolt-on acquisitions. I mean, this is -- our priority is to reduce that debt. Now that said, it's not a priority where you say when you have a great opportunity that we think is value generative and helpful to all stakeholders. We're going to pursue that, and I think the best example of that is the ongoing situation with Synergy, whereas Joe reported in his remarks, we put in a stocking horse bid. It's \$200 million. If we were successful at that level, I'm not suggesting that's how that will sort out, but if we're successful at that level that \$1 billion, \$200 million of it would definitely be allocated to business development, and there are other smaller items that throughout the year, we would expect to pursue to continue to add to our R&D portfolios or to our marketed portfolios for each one of our core and important business. So it's a very difficult question because in the absence of something value generative, we're going to reduce our debt. That's super clear. But if there are these opportunities that we chipped in, deploy them against business development, and it makes sense, we're going to do that and in my opinion like, for example, the Synergy thing, that is something that makes an incredible amount of sense based on the strategic fit within our Salix portfolio. So that we will allocate capital to -- for BD and other small things. I don't know if I answer you. I can't answer your question specifically, but I hope I provided at least the way we're thinking about it.

Operator

The next question comes from Irina Koffler of Mizuho.

Irina Koffler

I just wanted to verify that your guidance for next year, does it include any benefit from TRULANCE or any sales force expansion to Salix?

Joseph Papa

The guidance that we give does not include any M&A, to be clear. It does include our plans for XIFAXAN, but not specifically related to what we are planning for incremental sales reps or anything along those lines if we are successful in acquiring TRULANCE. Is that clear?

Irina Koffler

Yes, and then just one follow-up. You're obviously doing very well in Solta and cosmetic dermatology. Is there any thought to expanding your presence in that segment?

Joseph Papa

Yes, Paul made a comment that we have a leader there, Tom Hart, who's doing a absolute phenomenal job in turning around that business, and what we are -- what he's doing is he's really focused on a couple of things. Number one, launching some new products. He's got a new Thermage product that he's launching, and it's doing very well with that product launch. Number two, he is looking at what I would refer to as geographic expansion. He is looking at places where we have an opportunity to do better than existing business, so we do very well in the United States. We do very well in Asia, but we have a significant opportunity in Europe as an example. So Tom is putting some incremental resources to work there to up -- look at what we think is a good opportunity for growth in the European and some of the other areas of the world that we just are not as well represented. So we do think there's some opportunities, a lot of upsides to be clear based on what we think is really strong leadership by Tom Hart and the team.

Paul Herendeen

Yes, I want to -- it's Paul. I want to follow-on that as well is I think, the best way to build value is to optimize what you own and what you have in your own internal pipeline. And I daresay before Tom joined us and he was brought to us by Tom Appio, who runs our international business, which was a great thing for us. We had not optimized our existing portfolio nor where we positioned to optimize the new products that we already had the ability to roll out on our own and drive organic growth. That's why i.e. Joe, you can hear his enthusiasm about this business and certainly mine as well. We've called it out a handful of quarter -- quarters in a row here. We have an interesting portfolio. If there are opportunities to add to that, we surely would. But we have a lot of opportunity within that existing portfolio plus new products that we're rolling out from our pipeline. So well positioned in Global Solta.

Operator

Our next question comes from David Amsellem of Piper Jaffray.

David Amsellem

So just have a couple. So just coming back to M&A. I may have missed this, but maybe you can put a number on deal capacity or what you're wherewithal is in terms of deal size or aggregate transaction size and how much is earmarked for transactions. That's number one. And then number two, just talking about the cash pay dermatology model, can you just talk about the mechanics here? I mean, is this going to be products primarily dispensed in the physicians office, like what the Obagi model was and how many medical derm products do you envision falling under this model and then lastly, on the rifaximin studies, you highlighted four. Maybe give us some color on timing for data readouts on those studies?

Joseph Papa

Paul, why don't you take the first one? And I'll take the cash pay and rifaximin.

Paul Herendeen

Yes, sure, I mean -- David, thanks for the question. It's hard to put a number on what we might be willing to doing in M&A. We obviously have a limited capacity because of the level of our debt and limitations of our ability to generate free cash flow, which we can choose to either use to reduce debt or to deploy against the value-generative BD opportunities. I daresay, if we do Synergy this year it's going to be the -- that takes a good amount of our capacity out for 2019. If we're so fortunate as to be able to conclude that deal, it is one of the challenges that we face as we are a company that carries a lot of debt. We are highly levered and so we need to be incredibly judicious in the deployment of capital for BD, and it's just -- we don't have a big checkbook. We just don't, and that's the way it is until we can change it. And I'm not sure I answered your question, but I can't give you and say, oh, it's 40% of whatever. It's not. It's based on our ability to balance between the absolute requirement that we continue to prioritize using cash to reduce debt and not -- and being willing to place strategic bets on situations that we think are really going to be good for us in the long term.

Joseph Papa

David, on the second part of your questions about the cash pay model and dermatology. What we're trying to solve here is what the problems are in the dermatology space and some of the products, especially in areas like acne, for example, there is an uncertain environment with prior authorizations. There is uncertainty there for both the physician and the patient. There is expensive co-pays often in that category, and there is variable formulations from the generic companies, especially in the topical products. What we are going to seek to do is to bring forward a brand formulation that we believe will have predictable access, in other words, your patients will know, physicians will know how to get it, either through the physician's office, through retail stores or through a mail-order facility.

So predictable access, and it will have known pricing, very predictable pricing otherwise, we'll be able to give our belief that we could make this product available at a set price. So that's what we think will be very helpful to a large number of patients and physicians because the market will become very predictable versus what -- unfortunately, we see today is a very unpredictable market. So Bill Humphries, our leader in this derm business is moving forward with this. We have a lot more to say about specific products but think about some of the older products that we have in the areas of acne, also in some of the topical dermatitis and other areas that will be coming forth with our products. So a lot more to say about this as we roll it out, but we think it's a good way to look at it. On the third part of your first question was rifaximin.

You can hear our excitement that we're doing two things. Number one, coming out with the new formulations, and then number two, coming out with the new indications. So I don't know I can go through all of the specifics on the call now because there is a lot that's going to go on there, but I'll try to hit the highlights. In the post-operative Crohn's disease, it's a Phase III trial. It's using the EIR product that we are partnering with Alfasigma. I remind you that we had an arbitration with Alfasigma, and we found a solution to that. We resolved that. Good work by our business development and legal team, and we'll be headed into that Phase III trial with the post-operative Crohn's, and our expectation is we'll have data on that sometime in the, let's call it the 20 -- data sometime in the 2021, '22 time frame depending on what happens there. On the second area that we're looking at is the OHE study. That's the acute study I mentioned previously on the call. That's really, as I said, it's trying to look at the pharmacoeconomics of XIFAXAN, but importantly, giving us some information on SSD that we can then leverage and take into additional clinical trials. That will hit some data later this year, but I probably don't want to give specifics about filing or anything along those lines because that's something that we're still assessing over the long term. On the other area of SIBO, that as we mentioned is in a Phase II. There's a lot of patients with SIBO. We're looking at 17 million patients in the United States.

As I mentioned before, we're seeing somewhere approximately 12 million patients who were treating IBS-D. So it's somewhat of a subset of the SIBO population. So large numbers there. I don't have a specific date that I will share right now, but call it -- certainly, it will take a couple of years to get the data on that. And then we'll make decision that where we're going to go in there, but I think, certainly, in that 2021, '22 time frame for data and then where we want to be thinking about for the future. So I think, I've tried to answer all the questions there relative to your question on rifaximin study. We're very optimistic, and we are going to invest behind our rifaximin franchise.

Operator

And our next question today comes from David Steinberg of Jefferies.

David Steinberg

I have a few questions on your GI business. So first, back to XIFAXAN. Your unit growth has been steadily improving, I think, up to 8% according to IMS. You've recently had some positive data in pain associated with IBS-D and Joe, you mentioned that about 90% of the market is untapped. So just curious, now that you've settled with Teva and you have a runway for 5, 6, 7 years what sort of unit growth -- given these dynamics what sort of unit growth you think you can put up in the near to medium term for XIFAXAN given it's your biggest drug? And then secondly, on Synergy, what sort of sales -- it's a good strategic fit, but what sort of sales would you need to achieve assuming you get it to start turning a profit, and what sort of PK sales expectations would you have for TRULANCE? And then finally, Cosmo is now been approved for rifaximin in the case for traveler's diarrhea. From what you can see in the market, are they taking share and what's your view on any off-label prescriptions or indications like IBS-D and HA?

Joseph Papa

Sure. I think you got a lot of questions in there David, but I'll try to -- if I don't catch them all, let me -- remind me. On the first one, though, we're very excited to what we're seeing with XIFAXAN. The only thing I'm going to comment on is at least during the month of January, we actually saw about 10% growth in our year-over-year growth with XIFAXAN, so very strong unit in growth and as I mentioned in the nonretail segment, we're seeing even higher growth. So very excited about it, but just in terms of what we're expecting over the long term, I think it was really the nature of your question. I think if you think about volume growth in XIFAXAN, somewhere in that like, call it high single digit that's probably what I would stick with, not going into that double-digit side. Obviously, if we can get some additional net pricing, it might help grow -- show even more but high single digits is the unit volume growth I would probably think about as you're modeling.

On the question of Synergy, I think, I said in the call, we're really excited about it. We think there's a great opportunity there with Synergy, especially given the fact that we bring some important experience we have experienced in the gastroenterologist office, which we think is helpful to what we need to do with Synergy. Number two is we've got a great supply chain capability. Dennis Asharin and the team, both of you are doing really well on the supply chain and then we've got some problems we have to fix with Synergy. So that is what we think is an important competitive advantage that we bring to this situation. And then finally, one of the areas that we were concerned about as we were watching externally was the market access side for Synergy. We think we also have new leadership in our market access team and a good market access team that can help us to get the appropriate opportunity for the future, assuming we can get Synergy at the right price. Final comment, question I think you asked was in terms of what's happening with Cosmo. I can say that our sales force has not seen any activity or sales presence in the gastroenterologist or primary care offices from Cosmo. We can say with conviction, we know there are some significant barriers to entry in the GI offices, and we're very pleased with our position for rifaximin and specifically, XIFAXAN as we sit here today, but we have not seen anything from Cosmo at this time, in the marketplace. I think I got all your questions David. Operator, I think we have time for one last question.

Operator

Today's final question comes from Louise Chen of Cantor.

Louise Chen

So I have two questions. First question I had was you've said that your Significant Seven products are expected to double again in 2019. Just curious which products are driving that? And are there any, in particular, that you're very excited about? And then secondly, are you still considering options to meaningfully delever your balance sheet? And if so, what are some of those key options that you're considering?

Joseph Papa

Sure. I'll take that first part and then Paul, you want to take the comment on the second part of delevering. On the Significant Seven, I think, probably the best way to say it is that we like all the 7. We think all 7 of them are really the opportunity for growth, and we put them together specifically because as we talked about going back to 2019, they were under, call it, \$75 million of revenue, and we thought about what was going to drive the growth of our business, and we said, these 7 products are going to be key to us. Clearly, there's a big, big opportunity in dermatology as we bring SILIQ to the market. We get BRYHALL approved and upon the approval of DUOBRII, we think those 3 products are going to be an important driver not only of our Significant Seven but also the turnaround in dermatology. So I'd have to say that those are clearly important drivers to our future success with our dermatology turnaround. But we do think just to summarize my comment, all 7 products are important to us for the point of view of both the growth aspects, but also how we'll turn around the overall dermatology business. Paul, do you want to take the second part of Louise's question?

Paul Herendeen

Yes, sure. I mean, obviously, the best way is for us to delever or grow our adjusted EBITDA. Secondly, to prioritize use of cash flow to continue to reduce that debt. And last on that list would be to consider potential equity or equity-linked securities. I'd say that we have made an enormous amount of progress in managing our cap structure, particularly the liability side of our cap structure over the last couple of years. Great leadership from Will Woodfield, our treasurer. It's -- right now, we're okay with where we are leverage wise, and if we look at our forecast over the next few years, we will generate enough cash to help us significantly advance the ball and reducing our leverage in addition of the obvious benefits of growing our adjusted EBITDA. So we feel pretty good about where we are right now and not compelled to do anything. We'll just continue to look at for managing the cap structure side at opportunities to continue to target those debt stacks that come due. I mean, even though we've made such great progress I'll -- looking out to 2023, where there's a hefty amount of almost circa \$6 billion of unsecured debt that comes due out there that we want to start looking at and thinking about taking that out. But in terms of steps that its stay the course, let's grow our EBITDA, let's prioritize use of our cash to reduce debt, and we'll see how it goes.

Joseph Papa

Thank you, everyone, for joining us today, and look forward to having a chance to catch up with everyone over the next weeks ahead of us. Thank you. Have a great day, everyone.

Operator

And thank you, sir. Today's conference has now concluded. And we thank you all for attending today's presentation. You may now disconnect your lines, and have a wonderful day.

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