

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 paydown in the story, I guess, in general, should we still think about most of your cash flow being allocated to debt paydown 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. 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

<https://seekingalpha.com/article/4242568-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2018-results-earnings-call-transcript>

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 dermatology 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

<https://seekingalpha.com/article/4242266-bausch-health-companies-inc-bnc-ceo-joseph-papa-on-q4-2018-results-earnings-call-transcript>

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 BRYHALI 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.<https://seekingalpha.com/article/4242568-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2018-results-earnings-call-transcript>

