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TEVA.TA - Q4 2017 Teva Pharmaceutical Industries Ltd Earnings Call

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OVERVIEW:

Co. reported 4Q17 revenues of $5.5b and non-GAAP diluted EPS of $0.93. Expects 2018 non-GAAP EPS to be $2.25-2.50.

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PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and thank you for standing by, and welcome to the fourth quarter 2017 financial results. (Operator Instructions) I must advice you this conference is being recorded today, Thursday, the 8th of February 2018.

I'd now like to hand the conference over to your speaker today, Kevin Mannix, Senior Vice President, Head of Investor Relations. Please go ahead.

Kevin C. Mannix - *Teva Pharmaceutical Industries Limited - Head of Global IR & VP*

Thank you, Tracy, and thank you, everyone for joining us today to discuss Teva's fourth quarter and full year 2017 financial results. Earlier this morning, we issued our press release detailing our results for the quarter and year. Copy of the press release as well as the copy of the slides being presented on this call can be found on our website at www.tevapharm.com as well as on our Teva Investor Relations app. Our discussion today includes certain non-GAAP measures as defined by the SEC. Management uses both GAAP financial measures and the disclosed non-GAAP financial measures internally to evaluate and manage the company's operations to better understand its business. Further, management believes the inclusion of non-GAAP financial measures provides meaningful supplementary information to and facilitates analysis by investors in evaluating the company's financial performance, results of operations and trends. Reconciliation of GAAP to non-GAAP measures are available in our earnings release and in today's presentation.

Today, Kåre Schultz, our Chief Executive Officer, will open the call with some remarks on our annual results, recent events and outlook for 2018. Mike McClellan, our Chief Financial Officer will review the fourth quarter financial results in more detail and discuss additional assumptions around

our 2018 outlook. And I'd also like to note that on the call with us and available during the Q&A is Brendan O'Grady, Teva's Head of North America Commercial. And with that, I'll now turn the call over to Kåre. Kåre, if you would please.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Good morning, everybody, and thanks for calling in. Before we start, please read our cautionary note regarding forward-looking statements. As Kevin said, I'll address the full year. And if we start looking on the revenues, then revenues came in marginally above 2016, and there was, of course, a combination of the full inclusion of the generic sales in the U.S. and then some downward pressure on COPAXONE in these numbers. The operating income came in slightly below and as well the net income. If you look at the earnings, we came out with a non-GAAP result of $4 for the full year, which is in line with the predictions we had in the outlook after the third quarter. If you look at the GAAP results, then you'll see similar revenue, of course, and then you'll see a significant loss on the operating income, and this is related to a significant impairment of the goodwill in the U.S. generics businesses primarily, but Mike will get back to some of the details later.

If we look at the cash flow, which is of course important in a situation where we are deleveraging and reducing our debt on an ongoing basis, you can see that the net cash flow, including divestitures and also the free cash flow came in nicely, so that we were able to continue the reduction of our debt in 2017.

One of the key elements of our business outlook is our restructuring plan, which we revealed to all of you mid-December. The short message on the restructuring plan is that everything is on plan, everything is on target, but let me give you a bit of flavor to it. We have our new organizational structure in place, all levels down in terms of managing teams, and it's this new organization that has created our annual operating plan for 2018, which forms the basis for the guidance that we're giving you all today.

We have planned, as we communicated in December, a reduction of our global workforce from 53,000 to 39,000. So a 14,000 persons' reduction. Half of this reduction is expected to be completed by the end of Q2 of this year, and the remaining half would be over the following 6 quarters throughout '18 and '19. Everything is moving according to plan, and despite the fact that we have seen some onerous in Israel, which is now completely calm, we don't see anything that will block us from executing exactly as planned.

This includes a lot of closures and divestments as we've alluded to before. In this period here, we have had 6 announced closures of plants since we announced the restructuring plan, and we're expecting to announce another 6 plants by year-end of this year. But this is, of course, an ongoing process to consolidate our manufacturing footprint across this, which will go on all the way to '19, but also during the following years. We've also communicated that we are working on an optimization of our generics portfolio on a worldwide basis and in the U.S. I'm happy to inform you that we're, of course, doing this in a very constructive way talking with our key customers, discussing the issues and making sure that we find a solution regarding unprofitable products either in the form of price adjustments or discontinuation of the products from our side. We also have taken a very close look at all our R&D programs. And in the specialty area, we have cut roughly 27% of our programs. Basically these are programs that fall outside our core expertise area and where it's very speculative whether we would be able to return a profitable investment out of these programs. And we have also trimmed our generics portfolio. We have the world's largest portfolio of generic filings, and we've done a reduction there of a minor scale, but still it's 100 programs. The short message is, we are on track to achieve the $3 billion spend base reduction that we communicated earlier, and that more than half of this will happen in '18, and the full amount will be realized in 2019.

In terms of growth drivers, one of the key growth drivers is, of course, our specialty assets. And as you know, we have launched AUSTEDO last year. AUSTEDO is launched for both tardive dyskinesia and chorea in Huntington's disease, and it was launched first for Huntington's and later on for tardive dyskinesia. It's doing very well. We are accumulating patients exactly as we were planning. So we're very optimistic about the future growth of this very important product. We're also doing further clinical trials in Tourette basically in order to broaden the clinical basis for this product and thereby also increase the growth potential in the marketplace. This year, we are all very much focused on fremanezumab. We have a PDUFA date in June '16. As you know, we bought a voucher so we had an expectation that we will see a very fast handling of the review process from FDA, and we are actually seeing that. We are, of course, in constant dialogue with the FDA and they are moving ahead very nicely with inspecting the different elements such as the clinical elements and the finished manufacturing, and that is all looking very, very well. We have 1 new issue that we are flagging here. And that is the fact that our API is manufactured by our partner Celltrion in Korea. They have received a warning letter, and we are in active dialogue with FDA in order to ensure that this warning letter would not affect the supplies of API from Celltrion to our fremanezumab

program. We are optimistic that we would be able to prove that the API manufacturing is in good shape, but it, of course, remains to be settled in a discussion with FDA.

We are also here working to broaden the clinical basis for the products that we -- are in Phase III with cluster headaches, and we are starting an early Phase II program on post-traumatic headache, all very exciting and huge potentials. In the area of Pain, we have a collaboration with Regeneron on fasinumab. This is a very exciting product, which will be able to handle pain in osteoarthritis and chronic lower back pain. We're in Phase III, and we are looking forward to seeing the results in the coming years on this very exciting product.

I've mentioned before that it's very important for us to secure the cash flow, and the reason for that is, of course, as you all know that we have significant debt. And as I've told many of you, I don't really like a company like ours to have this much debt as we have, and therefore, we simply have to reduce it and we are working hard on that. And here you see the sort of debt facing us in the coming years, and here's a small footnote that's just to communicate that we are reducing the debt on an ongoing basis. And since the end of last year, which are the bars you're seeing here, we've actually reduced the debt by $1.1 billion in little more than a month that is past incident. Unfortunately, we won't keep that speed exactly. $1 billion a month going forward would have been nice, but it will be slightly less as you can see from the expected cash flows we have. But we are optimistic that we will keep on reducing it, and we have several liquidity items that are positive. We are getting $700 million from the Allergan settlement, and we have strong organic cash flow. And we have also renegotiated our covenants in order to make sure that we have the needed financial flexibility to keep on reducing the debt in a very stable situation.

With regards to the outlook for the full year 2018, you will see here that we're expecting a significant reduction of revenues. There are really 4 main reasons for it. We would say a fourth of it is structural. These items like the Women's Healthcare that we've sold off, some distribution businesses we've sold off, the Venezuela business that we have deconsolidated and so on. That's roughly a fourth of the decline. And then you have another fourth, which is roughly the generics, the price ratio we've seen in the U.S. and also some of the changes we've seen in Japan. And then there's roughly half the decline, which is related to the generic competition on COPAXONE. This, of course, also leads to a drop in operating income. It's less than the drop in revenues. One of the reasons being that we are expecting to see half of the effect of our restructuring program come in as a $1.5 billion reduction of the spend base. Of course, that will be more in '19 where it goes up to $3 billion. EBITDA is between $4.7 billion and $5 billion what we're expecting, and the EPS between $2.25 and $2.50. Free cash flow, which is, in this case, without potential divestitures that we might see later in the year, is coming out at $2.6 billion to $2.8 billion. With this review of the full year, I'll now hand over to Mike McClellan, who will look at the fourth quarter.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Executive VP & CFO*

Okay. Thank you, Kåre. Good morning, everyone. You've received a lot of information today in our press release, and I'd like to take the time I have to highlight what we think are some important areas of our results to focus on as well as to share with you some key assumptions that we have made for our outlook of 2018.

So turning to Slide 11. We start with a review of our GAAP performance, where we posted a quarterly GAAP operating loss of $13 billion in the fourth quarter of 2017. This is driven primarily from $14.3 billion of impairments, mainly related to the U.S. generic business in goodwill and other intangibles and partially offset by a gain on our Women's Health divested business and a onetime tax benefit that I'll go into later.

During the fourth quarter of 2017, we noted further deterioration in the U.S. generics market and economic environments, which included additional pricing pressure in the U.S. generics market as a result of the customer consolidation to larger buying groups capable of extracting greater price reductions. We also saw pricing challenges due to the government regulation, and a decrease in the value of our future launches as well as some other changes. As a result of this, we've adjusted certain of our assumptions used in the cash flow projections of the fourth quarter of 2017 to determine the fair value of our U.S. generics reporting unit. Based on this, we have recorded a goodwill of impairment of $11 billion related to our U.S. generics reporting unit in the fourth quarter of 2017.

So turning to Slide 12. For the non-GAAP adjustments for the quarter, we had net adjustments of $12.5 billion. This includes the $11 billion impairment of goodwill that I just discussed related to our U.S. generics business as well as additional impairments of other long-lived assets of $3.2 billion, mainly related to a revaluation of generic products acquired from Actavis, discontinued Actavis generic products and Rimsa products

as well as Teva-Takeda products and marketing rights for certain products. And in addition, we also had an impairment of some property plant and equipment of about $302 million.

Additionally, during the fourth quarter, we concluded that based on conditions in Venezuela, we are not deemed to have control over our subsidiaries, and this has led to a charge of nearly $400 million in connection with our deconsolidation of the results, and the primary driver of that is the cumulative currency translation adjustments we had related to Venezuela.

We also had a gain on tax-related items, primarily driven by the revaluation of our net deferred tax liabilities following the Tax Reform Act in the U.S. that was signed in December.

So looking at our non-GAAP performance on Slide 13, we see a decline of revenues of $1 billion or roughly 16% compared to Q4 2016, which I will drill down to on the next slide. What I would like to highlight here though is the fact that while sales are down significantly, our cost of goods are relatively flat. This is mainly attributable to the low level of cost of goods associated with the revenue that declined significantly, mainly driven by price erosion in the U.S. generics, COPAXONE, the impact of Venezuela and the nonrecurring $150 million upfront payment we had from Takeda that we received in Q4 2017 that are in our revenues. The non-GAAP diluted EPS for the quarter was $0.93. This is compared to our previously guided range of $0.70 to $0.80. The upside was the result of Teva's decision not to pay an annual bonus for 2017 due to the fact that the company's financial results were significantly below our original guidance for this year. As a result, there was a reversal of the amounts accrued for the bonus during the first 3 quarter and no accrual in Q4. Still, without this benefit, our results would have been inside the range guided of $0.70 to $0.80 per share.

Lastly, cash flow from operations for the quarter came in higher than our previous guided range of $850 million to $1 billion, actually totaling $1.2 billion mainly due to the higher collections from customers.

Turning to Slide 14. Revenues in the fourth quarter 2017 were $5.5 billion, down 16% compared to the fourth quarter of 2016. This is primarily due to a decrease in the revenues of our specialty medicine segment due to generic competition for COPAXONE as well as the absence of the $150 million upfront payment from Takeda that we had in exchange for our royalties and other rights, and Ninlaro which was booked under revenue in the specialty segment in 2016. We also saw a decline in our U.S. generics business due to the challenging market dynamics in the U.S. generics market. And lastly, adjustments of the exchange rate used for the Venezuelan bolivar compared to a year ago resulted in a net decrease of currency of $270 million, which is roughly $400 million decrease for Venezuela, offset by $130 million appreciation of other currencies.

Turning to Slide 15. We saw a quarter-over-quarter drop in the non-GAAP operating income of 29%, mainly due to the reduced sales of COPAXONE, the exchange rate differences driven by Venezuela, but these were partially offset by the expense savings, including the reversal of bonus accrual I mentioned earlier.

Turning to Slide 16. Global revenues of COPAXONE were $821 million, a decrease of 19% compared to the fourth quarter of 2016 and a decrease of over 17% compared to the third quarter of 2017, which was before the generic launch of Mylan 40 milligram generic in the United States. In the U.S., the revenues were down to $622 million, which is 20% drop compared to the third quarter of 2017, mainly due to the generic competition which resulted in higher rebates and lower volumes. At the end of the fourth quarter of 2017, COPAXONE 40 milligram accounted for over 85% of total COPAXONE prescriptions in the U.S., and the revenues outside of the U.S. were $199 million.

Turning to Slide 17. We see the cash flow from operations and free cash flow was strong for the second straight quarter after several onetime payments in Q1 and Q2. As I noted earlier, cash flow from operations benefited from slightly higher collections from customers, and I would note here that the free cash flow figures exclude any of the proceeds from divestitures, which we had $1.7 billion in Q4 of 2016 and $700 million in Q1 of 2017, as well as $1.8 billion in Q4 of 2018 related to the Women's Health sales. We also had proceeds from the sale of Mylan shares earlier in the year of about $700 million. We expect to use the bulk of our free cash flow in 2018 to continue to reduce our outstanding debt.

Turning to Slide 18. A few items to highlight on the balance sheet. We ended the year with approximately $1 billion in cash. Meanwhile, we see significant declines in goodwill and intangible assets due to the impairments in the fourth quarter, which I have reviewed earlier in my presentation, mainly related to our U.S. generics business. This led to a similar reduction in our shareholders' equity. Also as previously noted, we did see a

reduction in other long-term liabilities, due mainly to the gain on tax related to the deferred tax incomes following the tax reform in the U.S., and we also had a reduction in our debt that I will go in to in a few minutes.

Turning to Slide 19. As of December 31, 2017, our debt was $32.5 billion, a decrease of $3.3 billion compared to the $35.8 billion at the end of 2016. The decrease was due to debt repayments of our term loans, our revolving credit facility and other short-term loans of approximately $4.5 billion, which were offset by foreign exchange fluctuations of $1.1 billion due to the strengthening mainly of the euro.

We intend to reduce our debt further using the proceeds from a recently completed sale of the ex-U. S. Women's Health business for roughly $703 million as well as the onetime payment of $700 million from Allergan that we will receive as a result of the recently announced settlement agreement. Payment of that is expected during the first quarter of [2018] (corrected by company after the call).

So turning now to the financial outlook. Kåre has taken you through the numbers, but I think it's important to note some key assumptions that we have made in constructing this outlook. For revenues, there are 3 biggest factors are COPAXONE, U.S. generics and ProAir. Global COPAXONE sales are expected to be approximately $1.8 billion in 2018. This includes the ongoing erosion of the franchise from the recent generic competition and assumes a second generic launch of 40 milligram in the U.S. as early as April. U.S. generic sales consistent with the current segmentation are expected to be approximately $4 billion, a decline of roughly 20% versus 2017 due to ongoing price erosion in our base business as well as other products that have enjoyed periods of exclusivity, including the generic Concerta.

We also expect to see a generic competition for our ProAir franchise in the U.S. during the second half of the 2018. For our spend base, I'd like to note that we expect to show a net decline of approximately $1.8 billion from $16.3 billion in 2017 to $14.5 billion in 2018. This is the result of cost-saving initiatives, the effect of divestments and partially offset by negative currency impacts due mainly to the strengthening dollar -- strengthening euro and shekel versus the dollar. Additional assumptions on this include recent currency rates similar to those at the end of January 2018, which are roughly a dollar to euro -- a euro to dollar at $1.22 and the dollar to the Israeli shekel is ILS 3.41. We expect financing expenses to be around $900 million for the year, and our tax rate will be in the range of 17% to 19%, which reflects: one, the reduced sales of COPAXONE, which today benefits from a preferential tax rate; and two, the tax reform in the U.S., which is expected to have a negative impact on our overall rate due to the short -- in the short term due to the reforms kept on interest expense at 30% of EBIT in the U.S.

Our cash flow from operations for 2018 will include 2 large onetime items that offset each other. The payment of $700 million by Allergan to Teva as a result of the recently announced settlement and approximately an expense -- cash expense of $800 million in restructuring cost due to the program that Kåre mentioned earlier. We do expect capital expenditures during the year to be approximately $700 million, and we also expect our gross debt will be lowered by approximately $3.5 billion by the year-end 2018 coming from the free cash flow, the proceeds of the sale of the ex-U. S. Women's Health and other cash sources.

Lastly, the weighted average number of shares will be approximately 1,030,000,000. This is driven partially by the fact that we will be suspending the cash dividend on our preferred shares, as the recent goodwill impairment leaves us in a situation where we no longer have a positive retained earnings, and we will not be paying the dividend in cash, but rather paying them as accumulation at the end of the conversion period in shares. And that affects our share count over the course of 2018.

One last thing to note is that if we look at the quarters during the year, we're not going to give quarterly guidance, but due to the fact that we expect the second generic COPAXONE coming in April, you should expect Q1 to probably be the strongest of the year.

At this point, I'd like to then turn it over to the operator and take us into the Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of Douglas Tsao of Barclays.

Douglas Dylan Tsao - *Barclays PLC, Research Division - Director and Senior Research Analyst*

Just in terms of the comments in the press release, you referenced some worsening of the U.S. generic market in the fourth quarter. Do you have a sense of the impact from the WBAD joining -- or ECONDISC joining WBAD. And also just a comment, I might have missed in the prepared remarks, contributions from fremanezumab in the '18 guidance.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Yes. Thanks for the questions. I'll take the fremanezumab first and then Brendan will give you a review on the U.S. generics. In the guidance for 2018, fremanezumab basically has insignificant revenue, and that's simply because it's a launch that we are hoping to see sometime in the middle of the year and with a slow takeoff, which is the case for this new area where we'll see the expansion of the therapy, but not an existing market we're taking over. We have very modest expectations -- insignificant expectations for the revenue. However, it is an important product for us long term, since we believe that has huge potential in the migraine market. Brendan?

Brendan O'Grady - *Teva Pharmaceutical Industries Limited - EVP of North America Commercial*

Yes. Good morning, everybody. And thanks for the question. In regards to the U.S. generic market in the fourth quarter, I think it's just -- what we're continuing to see is the continued price erosion. I don't think that ECONDISC joining the WBAD group had really much to do with that. It's just a continuation of what we've seen in the overall market.

Operator

Your next question comes from the line of Louise Chen of Cantor.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

So first question I had was, what do you see as a longer-term vision for Teva and the growth drivers for Teva in 2019 and beyond? If you could elaborate more on that, that would be very helpful. What are your pushes and pulls on the generic launch side for sales and earnings in 2018. And the last question is, how do you think you can achieve historical levels of sales growth with the cost cuts that you've implemented for Teva?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Thank you, Louise. I'll try and actually combine your first and last question and then Brendan will give some perspectives on the U.S. generics. We think that we can return to historical growth after, you could say, the process of having COPAXONE go down in sales due to the generic competition and then having our new specialty products AUSTEDO and fremanezumab coming into the market and starting to accelerate into meaningful numbers. At the same time, we believe we can stabilize our generics and OTC business worldwide and increase the margin on that business long term by simply having a more profit-oriented portfolio strategy for that whole business. That does not mean that we expect to see significant revenue increases in our global generic business. But it does mean that we expect to see better margin developments over the coming years. So you would say we are sort of turning the strategy around from being a very volume-driven strategy to now being a much more profitability-driven strategy. The combination of a stable generics segment with increasing profitability, and COPAXONE basically stabilizing at a significantly lower level than where it was a couple of years ago, and then the new specialty products taking off. That's really what makes us believe that we have a strong future ahead of us. But, Brendan, over to you on the pulls and pushes for generics 2018.

Brendan O'Grady - *Teva Pharmaceutical Industries Limited - EVP of North America Commercial*

Yes. So if you continue to look at the generic market in the U.S. to 2018, I think that as Kåre mentioned, our goal is to stabilize the business. It is to stabilize the base business. And as we work through that, we have significant launches planned in 2018. We've already executed 4 of those launches and we will continue to do that throughout the year. So I think, overall, the -- we're very optimistic about how the business will transform in '18 and -- as we get control of that.

Operator

Our next question comes from the line of Vamil Divan of Crédit Suisse.

Vamil Kishore Divan - *Crédit Suisse AG, Research Division - Senior Analyst*

Just a little bit more on fremanezumab. I know you said you're in dialogue with the FDA regarding the approval. Is it produced at the same plant that Celltrion has the warning letter on? Or is it at a different plant? I'm just trying to understand your level of confidence, given the warning letter. And then the second one just more on the commercial side for that product. Curious if you can provide a little bit detail in terms of how you plan to present that commercially in terms of the type of device and the needle gauge? I noticed in the trials that were published in New England Journal as well as 30% injection site reaction with that product similar to what was in placebo on that trial also. But just curious if there is something that's going to change to bring those rates down in the real world?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Thanks for those questions, Vamil. I'll handle both of them. First on the warning letter that Celltrion got is for a large facility, which both includes, a, part of the facility, which is producing API, and another part of the facility, which is doing finished pharmaceutical manufacturing. And the comment in the warning letter and in the original 483 is really on the finished pharmaceutical part of the plant, which is what was inspected last summer when FDA inspected the plant. So you could say the warning letter and the comments have nothing to do with the API side, but it is the same huge manufacturing setup. So it is the same plant, you could say, but 2 different parts of the plant. We have had our own people there working with Celltrion. We have had external experts there working with them securing that all the manufacturing of fremanezumab is done in perfect GLP conditions. But, of course, it is an issue that they now have a warning letter and we need to see how we can reach an agreement on this with FDA and hopefully ensure that the PAI inspection of the API manufacturing will go ahead. And of course, all with the aim of keeping the PDUFA date for the product. With regards to injections and the commercial outlook, we are very confident in the commercial outlook of fremanezumab. As you might know, it is going to come in a completely sterilized syringe like most of antibodies come in the marketplace, and there'll be no problem doing self injection at home, if you want to do that, or go to a doctor and do there, if you want. There's no issue there. And you always see some level of injection side reaction on all products, but this is nothing that is cause of concern for us. And it's comparable to what you see on other similar products. What we do see as a huge advantage is that we are the only ones in this marketing space that has a product base you can take 4 times a year. That basically means that you can do this 4 days a year and then you don't have to worry about it the rest of the year, whereas the other products all only had once a month, which means basically 12 times a year and you need to go either to the doctor or the pharmacist or at home and take the injection. So I think this injection flexibility and this injection reduced frequency of injections is a huge commercial advantage that we have. And as you probably know, the efficacy on all of the products in development are similar. There's no real difference there. So having the same efficacy but significant more convenience, we think that would be a key edge for us in the marketplace.

Operator

Our next question comes from the line of Randall Stanicky of RBC Capital Markets.

Randall S. Stanicky - *RBC Capital Markets, LLC, Research Division - MD of Global Equity Research and Lead Analyst*

I just have a couple. First, just based on the amended covenants, it implies or at least seems to imply that EBITDA will grow annually going forward. So I just want to confirm, is that the case? And then what type of growth are you looking for? And where is that growth specifically coming from?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Thanks, Randall. It's coming from what I explained before. Basically, you'll see a pressure next year from COPAXONE still losing sales due to generic erosion. And then you'll see an uplift coming both from the top line in the form of AUSTEDO and fremanezumab, and then you'll see the uplift coming from the full implementation of the restructuring plan. So how that will exactly play out in detail in '19, it's difficult for me to quantify. But it's quite clear that the basic business plan we have for the next 5 years is, of course, for these uplifts to overtake the downward pressure from the COPAXONE generics and thereby getting us back into situations where we are growing EBITDA.

Randall S. Stanicky - *RBC Capital Markets, LLC, Research Division - MD of Global Equity Research and Lead Analyst*

Got it. So just to be clear, EBITDA in 2019 and 2020, we should expect that to be growing? And how about the revenue line?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

So that's -- like I said, for '19, it's too early to say because you'll have 2 different things happening at the same time, but you will expect the cost will decrease, so the implementation of the restructuring plan will take the spend base down. The specialty sales of AUSTEDO and fremanezumab will be increasing, and then we'll have a decrease of COPAXONE. But I can't tell you how big it's going to be because that depends on how big will the downturn on COPAXONE be in 2018. And that means longer term, it's for sure that COPAXONE will stabilize. The other 2 specialty products will be growing and will be reducing the spend base. That's why I'm answering that longer term, you'll see EBITDA growing, but it's hard for me right now to give you a specific number for 2019.

Randall S. Stanicky - *RBC Capital Markets, LLC, Research Division - MD of Global Equity Research and Lead Analyst*

Got it. Understood. And then Kåre, can you just comment on your ability to just focus on BD to help support medium-term growth over the next couple of years?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Yes. That's a very short answer because we won't do any big structural BD at all because we don't have the cash to do it and we don't want to do it. We want to consolidate, integrate and pay down debt. We might do some small early-stage in-licensing, but that's not really big time BD and that's not a lot of money. So of course, we're looking constantly to in-license exciting products that 6 to 10 years from now can reach the marketplace.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Executive VP & CFO*

Yes. And Randall, I would add to what Kåre said that when you're looking at those covenants, also remember we're expecting to pay down significant amounts of debt over each of those years. So that also helps with the leverage.

Operator

Our next question comes from the line of Gregg Gilbert of Deutsche Bank.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Couple of quick ones for Mike and then some generic questions. Mike, what nonoperating items, if any, are you including in the free cash flow guidance for '18? And can you give us AUSTEDO sales in the quarter? And then generically, I was hoping, Kåre, you could comment on in some more detail on the conversations you've been having with generic buyers on the subjective raising price versus discontinuation. And lastly, can you comment on your ability to file your generics Xifaxan again in the near term or ever? And lastly, why didn't you get Lialda final, given that you are -- you had a tentative and it could have gone final as far as we know last month?

Michael McClellan - *Teva Pharmaceutical Industries Limited - Executive VP & CFO*

So I'll take the first question. So basically, the way we've framed free cash flow is basically our cash flow from operations less our net CapEx. So the CapEx is reduced from that. If you look at special items in that free cash flow, we do include the $700 million we will get from the working capital settlement we did from Actavis -- from Allergan, but it will be offset by about $800 million of cash restructuring expenditure. So otherwise, it's really pretty much consistent with the net income that you will see driven in the free cash flow.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

With regard to the discussion with the key buyers, then, of course, I've been involved in some of those discussions and they are very constructive and positive, but it's really Brendan who is, of course, on daily basis, close to the customers. So I'll let Brendan give you some more light on that.

Brendan O'Grady - *Teva Pharmaceutical Industries Limited - EVP of North America Commercial*

Yes. Thanks, Kåre. So we've met with all 3 of the major customers and we continue to meet with our major customers, and I've explained the situation and what our intent there is. And I think that we have a good positive relationship with all of them, the discussion, the discourse has been good. And I suspect that we will wind up in 1 of 3 plays where there will be products where they will -- that are not profitable for us if they move to other suppliers. There is a group of products that we will be successful in increasing the price on to a profitable level. And there will be the third bucket of products that will work with our customers over a period of time to address this issue. Their goal here is not to create any shortages or disruptions in the market. And we pledge to do that with our customers. So I think we have a very good working relationship in -- as we move forward.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Can you say a few of the products?

Brendan O'Grady - *Teva Pharmaceutical Industries Limited - EVP of North America Commercial*

Yes. And on Lialda, we continue to work through the regulatory process, and we are working towards an approval and expect an approval on that product in 2018.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

And the Xifaxan filing lastly?

Brendan O'Grady - *Teva Pharmaceutical Industries Limited - EVP of North America Commercial*

Yes. So we're in active discussions with the FDA on that as well and we'll see where that goes.

Operator

Our next question comes from the line of Liav Abraham from Citi.

Liav Abraham - *Citigroup Inc, Research Division - Director*

Just a couple of questions. Firstly, given some of the comments that you made on your generics business in the U.S., can you just comment on what the pricing erosion was on the base business in Q4? And what your expectations are for U.S. base erosion of the generics business in 2018? And then secondly, on the gross margin, just based on my calculations, the implied gross margin for 2018 based in your guidance is in the mid- to high 40% range. Is that assumption reasonable? And Mike, maybe some comment on the key drivers behind this compression versus 2017. I'm assuming it's predominantly COPAXONE and partly generics. Can you comment on that?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Let me start by a general comment on pricing and price erosion. Going forward, we will no longer be giving specific comments on specific numbers for price erosion. And I'd like to just take a little time to explain the logic behind that. From a competitive point of view, sharing with your competitors and your customers details on your expected price development, to me, seems counterproductive from a competitive point of view. So this is partly maybe the reason for the downward spirals in the generics marketplace. It's like, if you say it's 10%, everybody will ask for 12%. If you say it's 15%, everybody will ask for 17%. And in my mind, that doesn't help our business. So going forward, we won't give any specific numbers on this, and I think that will help us stabilize the business. And we won't give you the details either on exactly how much is being discontinued, how much is being repriced and how we're seeing the overall price development. We will, of course, share with you every quarter the realized numbers, and we will also share with you broadly the total outlook we are expecting, but none of these pricing details. However, we don't have any problems with sharing what we talked about last year, and Brendan, you can give a comment on the Q4 erosion.

Brendan O'Grady - *Teva Pharmaceutical Industries Limited - EVP of North America Commercial*

Yes. So the Q4 erosion was pretty much in line with industry expectations, about 13%.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Executive VP & CFO*

Yes. So I can take the question on overall gross margin. So if you look at Teva as a whole, our expectations of gross margin percentage are roughly 50% next year. It's -- versus full year in 2017, we were closer to 55%. The 5 percentage point drop is driven mainly by pricing pressure on COPAXONE as well as pricing pressure in the U.S. generics. We also see a little bit of a currency impact there. You do have the results of the divested businesses coming out. But the majority of the 4-point erosion is really pricing on COPAXONE and the price erosion on U.S. generics, the base and the transition including Concerta.

Operator

Our next question comes from the line of Umer Raffat of Evercore.

Umer Raffat - *Evercore ISI, Research Division - Senior MD & Fundamental Research Analyst*

I guess, I wanted to focus on CGRP and ask, is it typical to have only 1 API source on a high-priority program like this? And how long would it take to either sign up a new API or resolve this warning letter? And then, if I may, what were the AUSTEDO sales in 4Q?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Thank you, Umer. So on the CGRP, we are planning to have more than one source. At this one moment, we only have 1 source, which is Celltrion. But we are planning to have actually one more supplier coming up and we're also building our own capacity. So longer term, we will have 2 suppliers. The second supplier is not ready right now. So we really have to resolve this together with the FDA and Celltrion. And we're optimistic that we can do that. If you think about how long it typically takes to resolve that warning letter, then you can say we've just done it ourselves in China successfully right now. And I would say, typically, it can take anywhere from 6 to 18 months to do it. That would be sort of a normal take on it. And then it's a little different to see from the day of the original inspection report or the day of warning letter, that depends on how active you've been working on it since the day you got the 483. So that is roughly the time lines that we are talking on. On AUSTEDO sales in Q4, I'll let Brendan comment on that.

Brendan O'Grady - *Teva Pharmaceutical Industries Limited - EVP of North America Commercial*

Yes. So AUSTEDO sales in Q4 were in line with the expectations and were $17 million.

Umer Raffat - *Evercore ISI, Research Division - Senior MD & Fundamental Research Analyst*

Kåre, if I may, are you saying AUSTEDO should -- sorry, are you saying CGRP should be approved 16 months -- 16 to 18 months from now? Or do you think your second API will kick in before that?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

No, I'm not saying that. First of all, what I'm saying is that the inspection that happened at Celltrion was in their finished pharmaceutical manufacturing, where they do the filling of products and the finished products. The part of the factory doing the API was not inspected and didn't have any warning letter or any comments to it because it wasn't inspected. We are working now to have a stand-up PAI inspection in connection with our file just like we've had the finished manufacturing is being inspected right now. That's actually with a supplier in Europe. And the clinical sites are also being inspected by FDA, so they're working diligently on this file. So in that respect, we hope that we can have a PAI of the API in Celltrion, and based on that, we can go into the marketplace. So it all remains to be seen how it plays out, but I'm not saying that it will be 18 months from now.

Operator

Our next question comes from the line of Jami Rubin of Goldman Sachs.

Jamilu E. Rubin - *Goldman Sachs Group Inc., Research Division - Equity Analyst*

Just have a couple. Mike, if you can just be a little bit more explicit on your year-end net debt forecast? You said you would be lowering it by $3.5 billion, but that's what -- from what, I think you ended 2017 at $32.5 billion, but when we read the press release last week, you had started to bring that down to around $30 billion. So where we're going to end at the end of this year? And if you could kind of talk about the past 2 net debt reduction going forward. And there's just another question. You just announced that you amended your covenants to now 5.9x from 5x and typically companies provide themselves with some cushion. But if I take the midpoint of your EBITDA guidance this year of $4.85 billion and apply that to a net debt number of, say, $28 billion, $29 billion and again, that's where I need your help. I'm getting at about 5.7 to 5.9x brushing up against your just announced amendment. And just wondering, if I'm looking at that correctly, whether you want to have a little bit more cushion

there? And then secondly, Kåre, if you could again be a little bit more explicit on timing of fremanezumab, that 16 months from what? From the original 483 letter? If you can just put that 16 to 18 months in perspective? And what is -- how likely is it that this fremanezumab could be launched on a timely basis? It seems like that would be pretty low.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Executive VP & CFO*

So I'll take the first couple of questions and then I'll turn it over to Kåre. So our year-end gross debt in our slides was $32.5 billion and we had about $1 billion of cash. So a net debt of $31.5 billion at the end of 2017. We do expect to pay down at least $3.5 billion that's driven by the free cash flow that you see in our guidance plus the $700 million from the ex-U. S. Women's Health sales that's not in the free cash flow. We will also look on top of that to see if we do additional asset divestments. We haven't put that in the outlook because we're still in the middle of looking at what could be of value to divest, but that is also part of our plans. If you look at the amended covenants, you're right that we did put it up at 5.9x. We agreed the covenants a couple weeks ago. In the meantime, we got the surprise news that the Pfizer plant that had been under a warning letter might come online a little bit earlier for a potential second COPAXONE 40 milligram generic. We still feel comfortable with our covenants, especially given the fact that we could do some asset divestments in 2018, but it's clear that we did need to move the covenants up. We feel very confident in that. We have a great relationship with our banking partners and that they gave us a wonderful support there. But it's something we're going have to manage very closely as we go into the rest of 2018. And then when we really start to see more of the restructuring plan in '19, that should give us an additional cash flow to help pay down debt. So -- and we feel confident, but there are things that we will be having to look at. And we will be looking to see if additional minor divestments can help pay down debt even more rapidly in 2018.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

And then Jami, I think maybe I didn't make it clear and maybe it was mispronounced by me. I said 6 to 18. So 06 to 18 months. It's typically the time it takes to close out a warning letter. So not 16 to 18, but 6 to 18. But that being said, the situation is a little more complex than it would normally be if it was just a warning letter on our manufacturing, because this is a warning letter on some manufacturing which is not related to our product because it's in the part of the factory that does the filling of finished products and so on. And we are in part of the factory where you do biologics, API manufacturing. So that's why I'm saying given the fact that we have used a voucher and that the FDA is doing everything possible so far to work in the PDUFA date of mid-June, we're, of course, in dialogue with them how we can ensure a PAI of the actual API manufacturing of fremanezumab at Celltrion. Now if we can secure that and if that goes through without problems based on all the work we have done, our quality people, there'll be Celltrion's quality people and of course, there'll be no delay of fremanezumab. On the other hand, if something pops up, and if there are some other issues, then there could be a delay. But I didn't say 16 to 18, I said 6 to 18. And that would be from the date of receiving the actual warning letter. I hope that answers your question.

Operator

Our next question comes from the line of Ken Cacciatore of Cowen and Company.

Kenneth Charles Cacciatore - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Just have 1 question on fremanezumab. Your competitors are going to be launching with auto injectors. Just wondering -- and you're indicating you're going to launch with the prefilled syringe. Are you working on an auto injector? The products, I don't think, are that differentiated. So just little things could matter. Just want to know if you are working to try to put your product into an auto injector?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Yes. There is very simple answer. Yes, we are. And we expect to have one within sort of -- we're launching in the short future. I don't think it's a huge difference and especially not for that segment who would like to have injections only 4 times a year. You would probably decide to go to the

doctors to begin with and have the injections at a clinic, and it's a standard prefilled syringe we have. It's no different from what's being used by millions of people every day. So we don't see it as a big issue for us, but of course, we will also have an auto injector.

Operator

Your next question comes from David Maris of Wells Fargo.

David William Maris - *Wells Fargo Securities, LLC, Research Division - Senior Analyst*

A few questions. So first, what are the number of products that you've cut that were unprofitable and the number of products that you raised prices on so far? Secondly, on R&D expenses were down quite a bit. Can you just walk through or give us some color on where those cuts are coming from? How you determined what to cut? And why investors shouldn't look at this and think that, that kind of impairs the growth going forward? And then lastly, does the 2018 guidance assume debt refinancing of the near-term maturities?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

So I'll take the 2 first ones and Mike can take the one about the debt. So in terms of the number of products, it's too early to say because we are right now in dialogue with our key customers and of course, we are discussing with them, like Brendan said, the options of either us adjusting the price and making them profitable again or us getting out of the contracts on them in a timely manner. But of course, we won't leave to any patients with our products. We won't sort of leave any customers without supplies, and typically our contracts are for an average of 6 months into the future. So this is something we can tell you more about once this year has passed, but we can't really tell you the outcome right now. With regard to R&D, I alluded to it a little bit by explaining that we have cut roughly 25 projects in our sort of the branded specialty R&D, that's roughly 27% of our context. And basically what we have done is, we've looked at where our core capabilities are, our core skills and kept all projects in those areas. So these are the areas, of course, of neurology, CNS and so on. And then we have said the more sort of blue ocean, more creative high-risk projects. Those we're taking out. If you look historically, then Teva has been very successful on taking good ideas within the space of neurology and CNS into its pipeline from other research organizations and then develop the projects, whereas it has not been our strength to do the basic research. And that means some of the projects where we've been doing basic research and where it's very sort of far away from our core competencies, we've decided to close those. And I think it won't really hurt the return on investment on our R&D investments and it won't hurt the future outlook of the company. In the space of generics, what we've done is, we've started to look at it more from a portfolio point of view. So look at the portfolio of NDAs, we had the portfolios of our ANDAs, we have -- which of these are the most valuable and which of these are very marginal in value, and thereby giving a more profitability-oriented way of building up our portfolio of generics projects.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Executive VP & CFO*

Yes. So when it comes to the 2018 outlook and debt refinancing, couple of things I would note here is that you may have noticed that we filed an S3 a couple of weeks ago. That is just normal and good corporate governance. We didn't have an active S3 at that time. But it is giving us eventually the opportunity to potentially come to the market with some debt offerings. Looking at our cash flows going forward and our debt maturities in the coming years, we are actively looking at potentially doing some refinancing of the near term. And the finance expenses that I mentioned in my 2018 outlook assumptions do include a little bit of an extra interest expense assumption for some minor refinancing in the $3 billion to $4 billion range, if we decide to do it.

Operator

Our next question comes from the line of Ronny Gal of Bernstein.

Aaron Gal - *Sanford C. Bernstein & Co., LLC., Research Division - Senior Research Analyst*

I'm going to touch, if you don't mind, if presenting that first, which is, is the facility that Celltrion have pays 2 facilities fees, one for the API and one for the filled finish? Or is it essentially 1 facility fee because obviously that will depends -- move things regulatorily? And second, your CapEx is still running around $700 million. It's been a long debate why Teva's CapEx is so much above other generic companies. Is this something that you're seeing opportunity to bring to like the $400 million or $500 million level overtime? Or is there still something that you expect to stay above kind of like industry norm longer term?

Michael McClellan - *Teva Pharmaceutical Industries Limited - Executive VP & CFO*

Ronny, can you just clarify in your second question what is you're referring to again on the $700 million?

Aaron Gal - *Sanford C. Bernstein & Co., LLC., Research Division - Senior Research Analyst*

The CapEx, capital expenses, sorry.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Executive VP & CFO*

CapEx, okay.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

So let me comment on the fremanezumab and the Celltrion facility. So the facility from a regulatory part of view is the same facility. It's a huge facility, but the part of the facility that was inspected was the finished and packed manufacturing site not the API part of the site. But from a regulatory point of view, it's the same facility site now so to speak.

Aaron Gal - *Sanford C. Bernstein & Co., LLC., Research Division - Senior Research Analyst*

Got it. So if you kind of look at that and look at the fact that the letter came to Celltrion on January 26 and they're telling them to higher consultants and view couple of independent assessment of compliance in that letter, is it realistic this will come in, in 6 months because they kind of look at this and just going to cycle time to do that has to be a little bit longer than that.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Yes, but the key issue for us is not exactly what timing it takes to close out that warning letter. The key issue here is that our manufacturing of API is happening in a completely separate part of the facility, which was not inspected by the FDA. So we will, of course, be in a dialogue with FDA, where we can hopefully conclude that it's a good idea to inspect that part in a PAI inspection and then based on the result of that, whether we can get the approval on time. But that all remains to be seen and we'll be in a dialogue with FDA about it.

Michael McClellan - *Teva Pharmaceutical Industries Limited - Executive VP & CFO*

Yes. Ronny, I can take your question on CapEx. The $700 million in CapEx we planned for 2018 is actually a decrease from this year. Though -- and it would have went down even further except we are spending a sizable amount to build the biologics plant in Germany. It's -- one of the key strategic moves that we're making for the coming years is to have our own large-scale biologics manufacturing. So absent that, we'll probably be more in the $500 million range, which you would see as more normal in the industry.

Operator

Your next question comes from the line of Chris Schott of JPMorgan.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Just a couple of quick ones here. First, maybe just coming back to the R&D spending. Can we just get a sense of with the restructuring you're doing here, et cetera, how we should be thinking about absolute R&D spending as we think about 2018 and 2019? My second question was on the CGRP and sorry just coming back to this, but just to help set some of our expectations, when do you expect to have clarity on whether or not the FDA is going to allow this approval despite the warning letter? Is this something which can wait for the PDUFA? Or do you expect, based on some of this dialogue, you'll be able to update us ahead of that PDUFA date? And then my final really quick question here was just on the timing of optimization. There is a 2018 top line guidance reflect much in the way of either product discontinuation and/or price increases on the generic portfolio? Or should we really think about portfolio optimization as more of a 2019 event as we think of the top line impact?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

Thank you very much, Chris. I'll do, I think, all 3 of them. So if you think about the R&D spending, then you could say we have taken a significant reduction on it as part of our restructuring plan. And we will not be giving you the specific number, but you could say it's about or close to $1 billion that we expect going forward. And we don't expect that to be dramatically different between '18 and '19, maybe slightly less in '19 compared to '18. And with regards to the CGRP, then what exactly was that you wanted to know?

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

The question is just based -- would you expect to have clarity from FDA prior to your PDUFA based on your dialogues? Or we really stand to wait for the PDUFA to see if this approach is going to be allowed?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - Former CEO & President*

I think, of course, we will know once we get to the PDUFA date. But I think the most likely is that we will give you an update once we announce our first quarter results. This is not something where we will give you ongoing updates because you don't do that when you're in a dialogue with the FDA. So I should expect that the next time you'll hear from us on this topic will be when we announce our first quarter results and when we have the color in that connection. With regard to the last question on the generics, then you could say both in '18 and '19, of course, we expect to see results of this process. The results we expect in '18 are included in our outlook. So -- but them -- very small in the sense that they have, of course, a slight negative effect on the revenue and a pretty much neutral to slightly positive effect on the earnings.

Kevin C. Mannix - *Teva Pharmaceutical Industries Limited - Head of Global IR & VP*

Well, thank you, everybody for joining us today. We'll be available throughout the rest of the week and next week to take any additional questions, and we look forward to seeing you all soon. Thank you very much.

Operator

Ladies and gentlemen, that does conclude our conference call today. For those of you wishing to review this conference, the replay facility can be accessed by dialing within the U.K. on (0845) 245-5205, or alternatively, on country code +44 1452 550000. The reservation number is 5279244 followed by the hash key. Thank you all for participating. You may all disconnect.