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TEVA.TA - Q1 2018 Teva Pharmaceutical Industries Ltd Earnings Call

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OVERVIEW:

Co. reported 1Q18 revenues of $5.1b, GAAP net income of $1.1b and GAAP EPS of $1.03. Expects full-year 2018 non-GAAP EPS to be $2.40-2.65.

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Teva first quarter 2018 financial results. (Operator Instructions) I must also advise you, the call is being recorded today, Thursday, the 3rd of May, 2018. I would like to turn the conference over to your first speaker today, Kevin Mannix, Senior Vice President, Head of Investor Relations. Please go ahead, sir.

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

Thank you, Steve, and thank you, everyone for joining us today to discuss Teva's first quarter 2018 financial results. Earlier this morning, we issued our press release detailing our results for the quarter and year. A 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 results, recent events and outlook for 2018. Mike McClellan, our Chief Financial Officer, will review the first quarter financial results in more detail and discuss additional assumptions around our 2018 outlook. 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 - President, CEO & Director*

Good morning, or good afternoon to all of you, and thanks for calling in. We had a strong start to 2018. The sales in the first quarter came out above $5 billion, USD 5.1 billion. And you will have seen that our earnings per share also came out strong. So the GAAP EPS came out at $1.03 and the non-GAAP EPS came out at $0.94. The free cash flow was also strong at USD 1.9 billion, and of course, there were several factors influencing this. One of the factors was the fact that our restructuring program is on schedule. It's doing very nice. I'll get back with more details about that. It's of course also important that our generic business in a -- is in a good balance. What I mean by that is that, as you all know, there will be products that are dropping off of the end of the lifecycle in generics and where prices are coming down. And then there'll be products that we are launching and that are coming in at healthy profitability in the beginning of the pipeline. And we've seen a good level of approvals and launches both in the U.S., Europe and in the growth markets.

COPAXONE is maintaining its share very nicely in the U.S. I'll give you some details on that. But it's really very steady at around 85% of the 40-milligram marketplace, and also in Europe, it's looking good.

AUSTEDO, that we launched last year, first for Huntington's disease; chorea; and Huntington's disease, the movement disorder; and then for tardive dyskinesia, another type of moving disorder, is continuing to grow nicely, and we see continuous growth in patients and also in revenues. And as a consequence of all these past developments, we have been able to reduce our debt, and the net debt is now down below $30 billion, which we see as a positive sign on our ability to keep on reducing debt also going forward. As a consequence of the better performance in the first quarter, we have raised our guidance for the full year. So we are now guiding that the non-GAAP EPS for the full year will be between $2.40 and $2.65. And we've also increased the guidance for free cash flow, and it's come up from $2.6 billion to $2.8 billion by $400 million to between $3.0 billion and $3.2 billion.

In terms of GAAP and non-GAAP, there's a few differences on the revenue line. Of course, that is no big deal. It's the same, and we have a development here from '17 to '18 where we have a reduction in revenues. And we'll discuss it a bit later. But it's primarily a combination of businesses that we sold off and of some decline in the COPAXONE and U.S. generic business that we have already commented on in previous quarters. On the operating income, you can see that there is slight difference between the non-GAAP and the GAAP in the sense that in the first quarter of '18, our GAAP operating income was $1.5 billion and the non-GAAP was $1.4 billion. And the same thing then goes down to net income where the GAAP is slightly higher than the non-GAAP. But basically, we made, on a non-GAAP basis, $1 billion in net income in the first quarter, and that is what results in the $0.94 per share.

So all in all, we're very satisfied with that, and we're also very satisfied with the total cash generated, which, in the first quarter, was USD 2.5 billion.

Now one of the elements that has been driving this development is the restructuring program that we announced back in the middle of December. And as you probably remember, the total target for the program in terms of reduction in the spend base is USD 3 billion. And it's our plan to realize half of that in the current year and the full amount by the end of 2019. And we are very much on track with that. And one of the key elements is, of course, the reduction in the total manpower of the company. And you might remember that, compared to the end of the third quarter, which was the basis for our restructuring plan, we had a plan to reduce the headcount by some 14,000 persons. And in the first quarter, we see here that we come out at a number which is around 46,000 in total, and that is roughly 6,200 less than when we started the plan.

So we are on track to achieve exactly the reductions we planned and that we set out for. If anything, it's going slightly faster than planned, but it's not a major deviation. But it does contribute a little bit to us having slightly lower cost than we were expecting in the first quarter. So that's a positive.

We're also doing a lot of changes to our manufacturing footprint, optimizing it, consolidating sites and divesting or closing redundant sites. And so far, we have announced 10 plant closures since December since we announced the restructuring plan.

On the consolidation side, we're also consolidating all other activities, such as R&D sites, headquarter sites, office locations and so on. So there's a massive activity ongoing, but it's all proceeding according to plan. And I'm very happy about the development on our restructuring plan overall. If we look at the revenue side, then of course, U.S. generics has been a big discussion topic and a big unknown for quite a while with a lot of changes

happening. I'm happy to report to you that when it comes to the volume, which is a starting point of any business, of course, then we see a very strong performance in the first quarter. We actually had more than 0.5 billion of scripts in the U.S. for our generic business, 583 million actually, around 15% volume share on the U.S. generic prescriptions. So that's, of course, positive. I know that you like to ask about the pricing, and I know you all remember, I told you that I wouldn't comment on it anymore with any specific numbers because I thought the generic industry had been doing a bad job on pricing and have been part of driving down prices. I can tell you that we are actually working on optimizing our portfolio with a strong focus on profitability. We're doing it in close collaboration with our key customers in a positive environment, ensuring stability in supplies and making sure that we can live up to the expectations from patients. But it does, of course, have the effect that we -- in our forecast, we see an adjustment of the total business we have in the U.S. That was part of what we announced at the beginning of the year where we said U.S. generics would probably sell around USD 4 billion for the year, and we still expect that.

One of the reasons why this is possible is, of course, all the new launches, and we are still, by far, the biggest in volume share but also, by far, the biggest in the number of product applications that are sitting with the FDA, also in terms of tentative approvals and first-to-files. So we think we have a very strong starting point for stabilizing and expanding profitability in our U.S. generics business.

You can see here on the slide the 10 products that we launched in the first quarter. And this is kind of the run rate we want to have and we need to have but also the one that we are expecting to have, broadly speaking, going forward so that every year, we can put enough new generic products into the marketplace to stabilize our U.S. generics business.

Another important element in our sales is, of course, COPAXONE. That's also nothing new. It's been also reviewed and discussed by all of you for a long time. And what you see here is sort of the raw data on how many scripts, what's the TRx volume. And as you can see here, it's kind of a boring graph because since the beginning of the year, it's completely flat around 10,000. And that basically means that there hasn't been any real change to our market share and to the mix between our market share and that of competition. We have roughly 85% of the volume in 40-milligram. And we maintain a very high level of access. Of course we've had to take a price hit. That's what you see in the turnover. We have reduced the price by increasing rebates in connection with the generic competition to the benefit, of course, of patients to get the products cheaper now. But as you can also see, we are basically hanging on to the volume share quite nicely. I'm sure there will be questions about what do we expect in terms of increased competition with COPAXONE. And of course, we do expect to see tougher competition later in the year. But so far so good. We're hanging on to the 85%.

Another thing that's exciting for us is AUSTEDO. I talked about it already. And if we take a look here, you can just see that we are accumulating more and more patients quarter-by-quarter. Our revenues are on target. We had $30 million of revenue in the first quarter. I mentioned already a quarter ago that the target we have for the full year is around $200 million, and we expect to get very close to that. And the reason why we see this potential in short term but also see big long-term potential is, of course, because there's a big unmet need. You can see how -- our estimates of the unmet medical need. We're talking more than 0.5 million persons in the U.S. who can benefit from this kind of therapy. So still there is a big potential market out there, and we're doing our best to grow it, and so far, it's looking good.

Now I'll talk about the business development and growth longer term. Of course, everybody's interested in fremanezumab. And we have, as you know, a voucher. So we are getting a fast review by FDA. We've had a very positive collaboration with the FDA, and we have 2 other companies also in that final stages of the review process with FDA. And we had a surprise, a negative surprise when our manufacturing partner that does the API, Celltrion, got a warning letter. And I'm happy to inform you that we are expecting now to see the preapproval inspection take place within the coming months. And this will have to go hand in hand with a reinspection of Celltrion, a warning letter reinspection. And of course, we have high confidence that both these inspections will be passed, and that means we will be able to get approval and launch before the end of 2018. At the same time, as you know, we have filed fremanezumab in Europe, and that's proceeding just completely standard. And we expect to see EMA take action on this. We expect an approval in the first half of next year. And just to remind you, in the competitive landscape, of course, there are 3 products that might launch this year, of which we are one. This is a new class that treats chronic migraine very effectively. All the 3 products basically have similar efficacy. But we do have one key benefit, and that is the fact that our product will most likely be approved for once-quarterly injection, which means that you only need to take your therapy once a quarter. We have proven in our clinical trials that, that's exactly the same efficacy as if you do it once a month, which is the case for our competitors. So we think everybody who wants a more convenient way of treating their migraine and achieve the same good clinical outcome will be sort of attracted to that we can offer quarterly treatment. So that's what I want to say overall on the business. And now I'll hand over to Michael McClellan, who will comment on the numbers. Over to you, Mike.

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

Thank you, Kåre. Good morning, everyone. You've received a lot of information today in our press release as well as the 8-K we furnished last week, with a lot of details in our new segment reporting. Following the reorganization we announced in November of last year, we have adjusted our segment reporting to align to the new organizational structure of the company. We are now organized by 3 regional segments, which have full P&L accountability as well as another noncore activities segment, which includes third-party API business. To assist you in your analysis, we have provided historical information for select revenues by activity in each of the 3 regions, and for your reference, it is in Slide #26 in the backup sections of this presentation.

In addition to this information, I think it's important to point out that -- the following, which I hope will help you in adjusting your historical models. First of all, our Canadian business, which had annual revenues in 2017 of approximately $590 million, including $476 million in generics, has moved from a Rest of the World into the North American segment. Second, our API business, which had approximately $750 million in revenue, is no longer included in the generic figures or in the regions, it is in the separate noncore segment. For your reference, about 37% of the API sales were generated in the U.S. in 2017, 36% in the growth markets and 27% in Europe. API is now under other activities, which also includes our Medis business, which had revenues of $445 million in 2017. Third, we moved the payments we received in connection with our agreement to sell the NINLARO royalty stream from Rest of the World to North America in the new segmentation. This includes 2 payments of $75 million each in quarter 1 of 2017 and quarter 2 of '17. And lastly, we had to reclassify Section 8 payments from Canada, which were once, in 2017, netted in G&A expenses but are now in other income. And you can see those done historically for all of the quarters of 2017.

I'd like to take the time now to highlight what we think are some important areas of our results and some more important details on our updated outlook of 2018.

So turning to Slide 12. As always, we start with a review of our GAAP performance where we posted a quarterly GAAP net income of $1.1 billion and an EPS on a GAAP basis of $1.03 in the first quarter of 2018. As we will detail in the next slide, the higher GAAP results than the non-GAAP come from a combination of some positive items like legal settlements offset by amortization and a few others.

So turning to our non-GAAP adjustments. You will see that we had several income figures as well as a few impairments. Please note that due to a change in the risk-free interest rates, we have adjusted our weighted average cost of capital by about 0.5%, which impacted several of these items leading to some impairments.

Starting with a $706 million of impairments, a portion was related to U.S. intangible assets, mainly due to the changes in fair value of generic products acquired from the Actavis Generics. In addition, we had a small impairment related to Rimsa, due partially to the change of our weighted average cost of capital as well as a change in allocated net assets to the Rimsa reporting unit. We also impaired a few assets that were transferred to Procter & Gamble as part of the PGT JV termination. And lastly, we recognized some accelerated depreciation in impairments related to site closures as part of the restructuring plan that Kåre mentioned earlier. In Q1, we also incurred $247 million of restructuring expenses as part of that program. And I do remind you that we expect a cash effect from restructuring programs to be roughly $800 million for the full year of 2018. We also had a series of gains in our GAAP P&L that were adjustments for the -- a couple of special items, including the sale of the non-U. S. Women's Health business, the Allergan working capital settlement, a settlement related to our purchase of Rimsa and a reversal of the GSK patent infringement lawsuit for Carvedilol, due to a positive judgement that we received.

Moving on to our GAAP -- non-GAAP results on Slide 14. Revenues for the first quarter were $5.1 billion, a decrease of 10%, mainly due to generic competition for COPAXONE 40-milligram in the U.S. as well as the market dynamics in the U.S. generic markets and a loss of revenues following the divestment of certain products and discontinuation of certain activities. The decrease in gross profit margin was mainly the result of the declines in the North American region, mainly due to lower COPAXONE sales and price erosion in the generics market, most of which were price impacts. Despite the aforementioned decline in our gross profits, the cost savings from our ongoing restructuring program softened the hit and allowed us to keep the loss in EBITDA roughly in line with the loss in revenues of 10%.

Free cash flow, excluding exceptional items, was $1.9 billion in the first quarter of 2018 compared to $0.3 billion in the first quarter of 2017. This is mainly due to the proceeds that came in from the working capital adjustment with Allergan, the legal settlement with Rimsa, and this compares

to a negative impact that you see in Q1 where we had payments for legal settlements, including the FCPA. On top of that, we also generated some proceeds from the Women's Health divestiture outside the U.S., bringing the -- us to a total cash generated of $2.5 billion for the quarter.

Turning to Slide 15. Again, we see the revenues in the first quarter of 2018 declined 10%. In North America, we saw a decline of $566 million, mainly due to generic competition to COPAXONE and the adverse market dynamics in the U.S. generics. In Europe, we had a solid performance, mainly due to new generic launches. In growth markets, revenues from better performance in Israel and Japan as well as an AZILECT approval from Takeda raised the sales in that unit. Divestments in other mainly includes the Women's Health divestments of $144 million quarter-on-quarter, the closure of a Hungary distribution activities, the deconsolidation of Venezuela and the nonrecurrence of the payment related to the NINLARO transaction in 2017, which was $75 million.

On Slide 16, we look at the non-GAAP operating income in the first quarter 2018, which is $1.4 billion, a decrease of 11% compared to the first quarter 2017. The cost savings from our ongoing restructuring efforts, which you see benefited all of the regions, especially, Europe, and growth markets, allowed us to partially offset the reductions in revenues in North America. And you can also see that the effect of the divestments mentioned on the revenues also had a negative effect of $156 million on the operating profit from 1 quarter last year to Q1 this year.

On Slide 18, we see EBITDA was $1.6 billion in the first quarter 2018, down 10% compared to the $1.8 billion in the first quarter 2017 but up 4% compared to Q4 2017. As we saw on the previous slide, we were able to partially offset the revenue decline in North America and the effects of the divestment with savings coming from the restructuring plan. Going forward, we would naturally expect to see a decline in EBITDA on the coming quarters when we see a full launch of the second generic competitor to COPAXONE 40 milligram in the U.S.

Turning to Slide 18, you can see global revenues of COPAXONE were $645 million, a decrease of 21% compared to Q4 of 2017. As Kåre mentioned earlier, our COPAXONE market share and volume have held up nicely despite Mylan's introduction of a 40-milligram generic in the United States last October, which has a -- had a greater impact on pricing than on volumes.

Free cash flow was $1.9 billion in the first quarter of 2017 compared to $0.3 billion in the first quarter of 2017. The increase was mainly due to proceeds from the working capital adjustment with Allergan, the legal settlement with Rimsa compared to negative effects of the FCPA and DOJ payments made in the first quarter of 2017.

Starting this quarter, based on the change in the accounting rules related to the classification of the retained portion of accounts receivables that have been secured, our cash flow from operations does not include these amounts, which totaled to $444 million in Q1 2018 as it comes through the Investing line in the cash flow statement. This has no net effect -- impact on free cash flow. The increase of amounts in the securitization this year from last year is related to the retained percentage that increased following our rerating to BB in late 2017.

So turning to Slide 20. Since the start of 2018, we've: one, renegotiated the financial covenants with our lending banks; two, issued $4.4 billion of new debt; and three, used the issuance plus the cash generated from free cash flow and divestments to reduce the company's overall net debt by $2.2 billion. And we've also extended the debt maturity profile that aligns to the future maturities that we expect to generate in the annual cash flow. As you can see in the additional information we've provided that we now have $700 million due for the rest of 2018, mainly Swiss franc loans that we will pay off in Q3 and Q4. And we have $2 billion in 2019, which we plan to repay with the net cash on hand and the free cash flow that we will be generating in the coming quarters. I'd also like to highlight the fact that we have no outstanding bank debt subject to financial covenants at the end of Q1 2018.

In terms of liquidity, I'd just like to point out here that our adjusted net debt-to-EBITDA ratio, which includes the impact of the divestitures being adjusted out, is at 4.68 at the end of Q1, which was a slight decline from 4.82 at the end of the year.

So for the financial outlook, turning to Slide 23. As Kåre mentioned in his opening remarks, we're increasing our full year guidance due to the strong first quarter performance, along with our confidence in executing the restructuring plan and delivering the rest of the year. This include the free cash flow that will be between $3 billion to $3.2 billion. As we think about the quarterly progression of our performance throughout the end of the year, we believe that the biggest single factor we'll see in the quarterly progression will be the impact of any future full second generic launch

of COPAXONE 40 milligram in the United States. So this concludes my remarks, and I'd like now to turn it back over to the operator who'll start the Q&A session for our call. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) The first question we have today comes from the line of Greg Gilbert from Deutsche Bank.

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

Kåre, I'm trying to get a sense of urgency or a sense of your sense of urgency to reduce debt. Obviously, you've done a good job so far with cash flow. But to the extent your turnaround continues to deliver on plan and the equity price improves, can you talk about your thoughts about using equity at some point to reduce debt to accelerate delevering and get back to playing some offense and being able to do some BD, et cetera? And my follow-up is for Brendan. Curious about the status of your generics Xifaxan program, saw the state get extended the other day. I'm trying to understand what that means in terms of your beliefs in approvability of your current application in light of the draft guidance, or the guidance at FDA.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

I'll answer the first question, then I'll hand it over to Brendan for your second question. So with regards to using equity, I've said it before and I'm pleased to repeat it again, I have absolutely no plans of issuing new equity. Basically, no matter what the price would be, the plan we have right now is based on, you could say, an organic improvement of the balance sheet by using our cash flows to reduce debt and by a strategy of consolidation and efficiency and profitability improvements over the coming years. So there are no plans for any kind of M&A activity or any issuance of equity whatsoever. We will simply use the operating cash flow we generate to reduce the debt over the coming years. So with that, I hope I addressed that question, and then I'll hand over to Brendan.

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

And now Greg, that was Xifaxan, right?

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

You got it.

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

Thank you.

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

Yes. So just a quick comment on Xifaxan. Obviously that is driven by the litigation in the approval, we had a 30-month stay that is over in August of '18. We're responding to the FDA's revised guidance around bioequivalence. So we've moved that out of '18 and do not expect a launch in 2018.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Okay. I hope that addressed your question.

Operator

The next question comes from the line of Jason Gerberry from Bank of America.

Jason Matthew Gerberry - *BofA Merrill Lynch, Research Division - MD in US Equity Research*

Just wanted to get a sense, your interaction with the FDA so far on the fremanezumab application. And what gives you guys, I guess, confidence in approval by year end? And have you guys had any advancement in terms of finding or securing a back-up API support source?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Jason, thanks for that question. I'll handle that. So first of all, we've had a very constructive dialogue with FDA, and we continue to have that. And it's pretty evident from the clinical data, we have an actually that of our [committers] as well. There is not much doubt about the efficacy of this class. It's very efficacious. It's a huge improvement in the health situation for people with chronic migraine. So we don't see any real issues on the efficacy and safety side. So the only, you could say, issue we have had outstanding or we still have outstanding is the fact that our API source, Celltrion, have had the warning letter based on the inspection they had last year where they got a 483. And we have been in discussions, of course, with FDA on this. And based on those discussions, we are expecting to see an inspection of their plant in the coming months. And of course, we're expecting that we will be able to have our partner meet the demands from FDA. And based on that, we are expecting to see an approval and launch before the end of this year. And we do not have any back-up source that we have filed with the FDA. So we are basically assuming and expecting that Celltrion will get in good shape in terms of GMP compliance. And we have no reasons to believe otherwise.

Jason Matthew Gerberry - *BofA Merrill Lynch, Research Division - MD in US Equity Research*

And Kåre, just to follow up. I mean, what, ultimately, makes you confident that the broader issues in the warning letter, beyond just fremanezumab, are resolvable? Is that something that you've gained incremental comfort on over the course of the past few months?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

You could say, my assessment is based on mine and then some of my colleagues and external experts' assessment of the outstanding issues mentioned in the 483 and in the activities undertaken by our partner, Celltrion, to remedy all these different deficiencies and make sure that they have a good state of the GMP compliance.

Operator

The next question today comes from the line of Elliot Wilbur from Raymond James.

Elliot Henry Wilbur - *Raymond James & Associates, Inc., Research Division - Senior Research Analyst*

Kåre, I just wanted to get a little bit more color around your commentary on the U.S. generics business optimization. Maybe a little bit more detail, kind of where you are in that process? I'm just sort of wondering, based on your interaction with customers, what's the -- what are some of the pushes and pulls in terms of customers be willing to accept or being told they have to accept the higher price versus risk discontinuation. And you're -- how willing are they to seize on price given what seems to be fairly large retrenchment across many major manufacturers in the U.S. and the potential supply chain risk that creates versus letting you out of somebody's contracts without having to be forced to pay a lot of inabilities?

Second question. Just wanted to get a little bit more color around the guidance increase in revenue, hard to get too granular on $200 million or 1% in revenue. But just curious if it's fair to say that the bulk of that is COPAXONE and FX.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

So Elliot, thanks for that. I'll give a little bit of color to the U.S. generics, and then I'll let Brendan give some more details, and then Mike will give you some answers on the guidance. But if we start with the overall situation on U.S. generics and pricing, I think it's really important to understand the basics of the dynamics that's been happening. And the way at least I've analyzed it, is that we had a consolidation on the buyer side, and you had a situation where suppliers were maybe accepting lower prices because they used to have a healthy margin and at least not all market participants, and definitely not Teva, wants to maybe totally on top of profitability product by product at a very detailed level. And if you then go into a semi-commoditized market and you take a raise to the bottom on price, then you will be destroying your own profitability. And the only way to sort of get out of that negative spiral is, of course, to stop it by saying, well, we are not in the business of volume, we're in the business of profitability. And then changing your course of action without, of course, harming any patients and without harming your customers. That's of course very important because these are -- we are the biggest supplier of medicine in the United States. We supply to more patients than anybody else. So we are very keenly aware of that responsibility, and we don't want to cause any disruption. But as the market leader, it's also us who are part of setting the tone. And I just thought it was really important to explain that we are not in the business of just supplying more and more volume for the sake of the volume. We're in the business of business and that is to have a profitable business. So therefore, we took these initiatives, and there's no risk that we won't be able to supply. That's not how we're doing it. We're simply doing a classical portfolio optimization exercise. And I'll turn it over to Brendan, and he can give you a bit more color on how this is progressing with our key customers.

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

Thanks, Kåre. And yes, I'll give you a little bit more color there. So we've met with all of our major customers and supplied each one of those customers with a list of products that we specifically wanted to address. And I will say that having worked through all of the issues we have, we're just about through that exercise. And it's really kind of like an 80-20 rule. About 80% of the products we will get out of, then they will move to other suppliers; and about 20% of the products, we will see an increase in price on. So we've been happy with the response from our customers. We've worked with them very cooperatively and responsibly. And the idea here, as Kåre mentioned, is not to create any kind of supply shortage in the market but to do so in a very easy way for them and for us as well. So we've been able to minimize or even eliminate any failure to supply penalties.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Thank you, Brendan. And then we'll move on to the guidance. And before we do that, I'll just remind you all that when we sent out the guidance a quarter ago for the full year, we had taken into account that this would happen in the U.S. So our $4 billion expectation for U.S. generics sales was inclusive of the loss of turnover as a result of their tail cutting. And of course, the reason why we do it is that there's no sense in selling products when you had a cash loss on doing it at the margin. So there's no real change in the guidance from what we saw a quarter ago and from what we saw now when it comes to the U.S. generics. But with that, over to you, Mike, on the $200 million up on top line.

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

Yes. So I'll tell you a little bit about why we raised the guidance both on the top line and the operating profit. So the $200 million on the top line is coming across the different regions. Europe has had a good performance, growth markets as well. We've seen a strong performance in the ANDA business in the U.S. COPAXONE is maintaining very well. So we're off to a very good start. It is only 1% on the full year, so it's not a major deviation. FX is a slight advantage there, but we did build our expectations on FX rates that are pretty close to what we've seen in Q1. So I don't see that as a major driver. We also have included the expectation that we will have a little bit additional cost savings based on what we've seen through the Q1. When you add all of that together, you end up with about $200 million both on the top line and on the EBITDA. And that's the basis of our guidance. So that's -- it's no one single driver. It's just strong performance across the portfolio.

Operator

The next question today comes from the line of David Risinger from Morgan Stanley.

Zhu Shen Ng - *Morgan Stanley, Research Division - Research Associate*

Zhu Shen here for David Risinger. Could you please discuss the R&D and SG&A cost reduction opportunities looking forward? Yes. That's it for me.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Okay. Thank you, Tsu Chin (sic) [Zhu Shen]. I'll handle that. Yes, you could say, in broad terms, what we've done and as we have sort of resized our portfolio and our R&D to what we think is sustainable and needed for a healthy business, and in broad terms, that's sort of ongoing, $1 billion in yearly spend on R&D, roughly 50-50 between generics and specialty. Of course, we have some elements, pilot scale, manufacturing upscaling, some clinical testing, whatsoever, where we have facilities that we use both for specialty and R&D. So we're seeing some synergies there by consolidation of the 2 branches of R&D, which we've done. This enables us to constantly produce enough new generic filings to keep our business going long term. And you could say the $0.5 billion in specialty R&D, in my mind, is enough to keep us going and having a couple of good hits. Not on a yearly basis but over a 10-year period, we will have several good hits, and we will have products like fremanezumab coming to the market, and products like AUSTEDO, like COPAXONE. These type of products, which will be high, high clinical-benefit, relatively high price in the specialty segment. And we think we can maintain that balance nicely with the current spending. We don't have any plans of further dramatic reductions below the sort of $1 billion level. But we don't see any reason why we would take it or buy over. So sort of for the coming years, that's really the level we are expecting. And Mike, you can just give some more clarity on it.

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

Yes. Let me give you some color. Our spend base reduction, we are planning to get to $3 billion by the end of the restructuring plan, we promised $1.5 billion in this year. If you look at Q1, the spend base versus Q1 of last year is actually down by a net $400 million. That is against a currency headwind of about $190 million. So overall, we were able to reduce the real operating and cost of goods by $420 million. We had a headwind against that of FX of $190 million. But then again, we also benefited from the divestment, which reduces the spend base. It's not part of our $1.5 billion net target that we're talking about. But you'll see, overall, the $400 million is -- minus $400 million in operating, plus $200 million in FX, and then another $150 million coming back out from the divestments.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Thank you, Mike. I think that covers the question.

Operator

The next question comes from the line of Irina Koffler from Mizuho.

Irina Rivkind Koffler - *Mizuho Securities USA LLC, Research Division - MD of Americas Research & Senior Analyst*

Market in terms of commercialization for AUSTEDO? And the second one is, for migraine, we heard at AAN that you would be considering using some of your primary care respiratory reps to promote CGRP. Can you just comment on that briefly?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Irina, I'm sorry but for some technical reason, I didn't get fully the first question on AUSTEDO. Could you just repeat it please?

Irina Rivkind Koffler - *Mizuho Securities USA LLC, Research Division - MD of Americas Research & Senior Analyst*

Sure. Are you planning to start promoting AUSTEDO to -- in the psychiatry market more aggressively?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Okay. Thank you very much. I will refer both the question on AUSTEDO and the CGRP and respiratory sales force question to Brendan.

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

Yes. So thank you, Irina, for the questions. So in regards to AUSTEDO, yes, we are increasing the amount of sales support around AUSTEDO to the -- to psychiatry group. And we did so just recently that sales force, that increase in FTEs will be out there in the first part of May. So we're there. As far as the question about fremanezumab and how we plan to promote that, we have 2 sales forces that will be promoting fremanezumab. One is a neuroscience sales force, and we've kind of restructured our respiratory sales force a little bit to allow some promotion there as well.

Operator

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

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

First question is on COPAXONE. Just given your experience with one generic 40-milligram on the market and the response of those customers and patients and payers, are there any changes to how you think this market will evolve with 2 generics on the market? Any change to your assumptions there regarding how the revenues will progress as a second generic enters the market? And then secondly, just on the CRL that Celltrion recently received for biosimilar Rituxan and Herceptin, noticed yesterday that Sandoz received a CRL for its biosimilar Rituxan. Was the Celltrion CRL only due to manufacturing? Or were there any other deficiencies noted in that application? And any other additional color you could provide there.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Thank you for those 2 questions. We'll handle the COPAXONE first. I'll just give a few general comments, and then Brendan can give you some more specifics. From an overall point of view, there's no real change in how we see it. You could say the best proxy we have for it is if you look at the 20-milligram where you have 2 players besides us. That each have a generic in the marketplace. And you can get some inspiration by looking at how much volume they've got by now. And then you can look to other markets where it's kind of a similar specialty injectable product that we're talking about, similar to COPAXONE. And my thinking is that we will, of course, see some further pressure on our pricing by the fact that there will be 2 generic 40-milligrams in the marketplace. And probably also marginal pressure on the volume throughout the rest of the year. And that's what we've modeled into our guidance as well. But Brendan, do you have any specifics? Any new thoughts on how that will play out?

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

Yes. Just a few things to add, Kåre. So I've been in this market a long time, and I've seen this market evolve. And I will tell you that I haven't seen any surprises as the way this market is shaped since 2013, 2014, as we've seen generic competition on 20-milligram as well as 40-milligram. So as Kåre mentioned, as we see another 40-milligram generic enter the market, I think there will be some downward pressure on price, probably a little

on volume as well. But today, we maintain about 85% of the overall COPAXONE market, and it is following our expectations and our plans for the year.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

With regards to the biosimilars. Then of course, the details, you will have to discuss with Celltrion. But it's so that we assess that the key issue in the CRL for both the products that we have licensed here in the U.S. from Celltrion is really the warning letter, and as such, we are expecting that with a positive reinspection in the coming months, we will be able to see Celltrion eventually lift the CRL and get approval. But our planning is such that we're planning to have these lunches next year, so it's really not something that's affecting the financial outlook for the current year.

Operator

The next question today comes from the line of Umer Raffat from Evercore.

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

I actually wanted to focus on 2 of your most important high-flying items. First, Regeneron said in their press release this morning that they're discontinuing the high dose of their NGF program. So I just wanted to get some update from you on what happened? What was seen at that high dose? Was it RPO, the neurosensory changes? And what does that mean for the overall program now because Teva -- because Pfizer really haven't seen much of their RPO advance from my understanding? And secondly, on CGRP, my question really is, you mentioned you expect an approval by year-end but not in June. So like mechanistically, how does that work? Because my understanding is, if it's a CRL in June, then you need to wait for an inspection, then refile, which may put a new clock. And I just want to get clarity there.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Thank you for those 2 questions. First on fasinumab. So the details, you would have to discuss, of course, with Regeneron. But as it's stated today in their release, what happened was basically that the independent data safety board that's overlooking the trials, they concluded based on an overall risk-benefit analysis that the high-dose arms should be -- or they recommended that the high-dose arms should be discontinued. And that's happening. And FDA is, of course -- has been updated on everything, and there will now be a dialogue with FDA with regards to the program. And so far, the trials are being modified with the high-dose arms being taken out of trials for fasinumab. With regards to the question on CGRP, then we are in a positive, constructive dialogue with the FDA, and we -- based on that dialogue, we do see a possibility for us having the approval and launch this year. I can't get into more specific details on that.

Operator

The next question today comes from the line of David Amsellem from Piper Jaffray.

David A. Amsellem - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

So just on fremanezumab, just thinking beyond the potential approval. So your competitors, among the monoclonals, are formulating it in auto-injector pens, and your product has relatively high volume compared to the Amgen and Lilly products. So I just wanted to get a sense of the extent to which you think you can formulate it over time in a pen device. And do you think that the relatively high injection volume could be -- could put you at a competitive disadvantage?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Yes. I'll give you the overall comment, then Brendan can give some more details. I don't think we have any disadvantage. We don't have a significant, high volume of the dosage. It's pretty complete standard like nearly other -- any other antibody that's given once a month. And it's comparable to what competition has. And with regards to the auto-injector then for device development reasons, which are not linked to the product as such, we don't have the approval of the auto-injector that we'll be using yet. But we are interested in moving ahead with that according to plans. So we expect to see that in the market. It's correct that if you get the therapy once a quarter, then of course you get a higher volume once a quarter. But it's very likely that their quarterly dosing will be taken place with a nurse or at the doctor's office with some assistance. And that in itself might be a preferable for a certain segment of the market. At least in my long experience with injectables, fewer injections seems to win over more injections. That's what I've seen in diabetes over the last 30 years, and it's also what I've seen in psychiatry over the last 5 to 10 years. So I'm very optimistic, there will be a significant part of the markets that will prefer less injections. But Brendan, do you have any color to add?

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

Yes. I think there's some confusion regarding fremanezumab and the dosing frequency. So as Kåre said, we will have a monthly as well as a quarterly. And the quarterly does require more injections, but it'll give the patient flexibility to have that injection either monthly at home, quarterly at home or quarterly in the doctor's office. And because it's quarterly in the doctor's office, and there's more than one injection, quite, I think, people are confusing that with our lack of a pen device at launch. So we do have a pen device in development. We hope to launch it after we obviously launch the product itself. And so there's no issue with the pen device. It's related to the volume of the product. So we think that we have a very, very competitive offering because we will be the only ones that have the quarterly dosing, and we think that, that will be both a benefit to physicians and patients.

David A. Amsellem - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

Any specifics on timing of the launch of the pen device?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

No. No specifics. It will be following the approval and launch of the product in a prefilled syringe. But we don't have any specific data on it.

Operator

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

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

Question for you, Mike, on debt paydown. You ended this quarter with net debt of $29.3 billion. Don't know if I sob but do you -- what -- where do you expect that to be by the end of the year? And just given the results this quarter, and clearly what seems to be faster debt paydown, can you hit 4x leverage by 2019? And is there an opportunity for further divestitures, which could speed up debt reduction?

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

Yes. So thank you, Jami. So, so far, we have paid down $2.2 billion, which is actually a gross paydown of 2.5, but the currency has gone against us by about $300 million. We originally said we'd pay down about $3.5 billion this year. I think, with the free cash flow guidance range, we will probably try to pay even more now. The currency, of course, will be the wild card in that. So I could see us going down another $1.3 billion to $1.5 billion by the end of the year. And we're still on track to meet our goal of 4x by the end of 2020. But of course, that relies on the fact of us generating enough cash to cover maturities in the next 2.5 years as well as seeing a stronger EBITDA as we go into 2020 and we get past the COPAXONE trough. So

we still feel confident that we're on track for it, but there are some moving parts that we will be keeping a close eye on and we will be managing over the course of the next 2 years. In terms of additional asset divestments, we're still looking at a couple of assets that -- we have made public that we are no longer really looking at the ANDA business. We're going to keep that and run it. We're still looking at Medis, and there's a few other minor assets. But we really don't see that as the huge lever to delever. It's really about generating organic cash flow and raising the EBITDA over time so that we can get our ratios down to where we want to be.

Operator

The next question comes from the line of Ami Fadia from Leerink Partners.

Ami Fadia - *Leerink Partners LLC, Research Division - Director of Specialty Pharmaceuticals & Generics and Senior Analyst of Specialty Pharmaceuticals*

I had 2 questions. Firstly, just a clarification on fremanezumab. You indicated that patients will have the option to either self-inject or have it -- have the dose injected at a health care professional's office. Now how would that impact how the drug is reimbursed between their prescription benefits versus something like a buy-and-bill? And secondly, just with respect to Celltrion, could you give us a little bit more color around what gives you confidence that they will be able to address FDA's questions around the warning letter in the coming months, thereby triggering another FDA inspection? Or are you really telling us that irrespective of whether or not they address their issues based on your conversations with the FDA, you still think that they'll come back for a reinspection for fremanezumab?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Thank you very much, Ami. I'll try to explain how we see the Celltrion issue first, and then Brendan will talk about the thing about the injections so -- and the reimbursement. So the way we see it with Celltrion is, of course, they need to be in a good state of GMP, and we believe that they are, and they have remedied the outstanding issues. But that's of course up to the FDA reinspection to assess that. And what needs to happen is they need to have a reinspection and there needs to be a PAI, preapproval inspection of fremanezumab API manufacturing. Now on the API manufacturing, of course, we've been following that closely for the last years since it's crucial for fremanezumab. The actual 483 that Celltrion had last year, in June I believe it was, was actually on their Finnish pharmaceutical manufacturing. And of course, they have done everything needed to remedy those deficiencies that they had, and they have, of course, had to inform FDA on an ongoing basis of what they were doing like any other manufacturer would have to do. And they had to report to the FDA that they have now completed their remediation plan as they are ready to take a reinspection. So they have, of course, done that, and that is why that we say that we expect that there will be a warning letter reinspection and a preapproval inspection in the coming months. And of course, then any approval and launch is then on the assumption that Celltrion has done a good job, and they are in a good state of compliance, and that FDA will find this when they do the reinspection and they do the preapproval inspection. And based on that, we're saying that we expect approval and launch before the end of this year. So I hope that clarifies it. Now Brendan, could you explain about self-injection and injection at the -- at a clinic and reimbursement and so on in the U.S?

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

Yes, sure. Just let me just jump in on that. So we expect that these products being self-injectable products will go through the pharmacy reimbursement. So we're not necessarily saying that this is a medical-reimbursed product, but these are all self-injectables. But they will also likely go through specialty pharmacy distribution. So I think what we're saying is that for patients that want a quarterly option and then may not want to inject it themselves and are likely seeing their neurologist or the physician for migraine once every quarter, that option exists, and there's a way to do that through specialty pharmacy distribution or other channels. And I really don't want to say much more about our reimbursement strategy other than that.

Operator

The next question today comes from the line of Rohit Vanjani from Guggenheim Partners.

Rohit Govind Vanjani - *Guggenheim Securities, LLC, Research Division - Senior Analyst*

I just wanted to -- I'm sorry, another question on fremanezumab. I think last time you had said, on the API site where that was being produced had not been inspected. So as part of the PAI, will this -- the inspection of the API site be the first time that, that's being inspected? And then secondly, you mentioned that 80% of products -- 80-20 rule, 80% of products moving and 20% taking a price increase, has that 80% of the products moved yet? And if not, is that a 2018 or a 2019 event?

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Okay. We would take some of the questions. I'll address the fremanezumab API thing, and the Brendan will give you a flavor on the U.S. generics pricing. So the preapproval inspection of fremanezumab, the way you have a preapproval inspection done on an API site is that you have to have your manufacturing up and running. So you got to make sure that you're actually producing fremanezumab when the inspectors come to the site, and they have a good look at everything that's going on. And since this is a preapproval inspection of a new product, then obviously, that process has not been inspected before. But of course, you can also judge from the portfolio that Celltrion has that their API facility as such has been inspected before. So that's really the situation on that one.

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

Yes. So let me address the other question on the 80-20 rule. So the list differs by customer. So there is some overlap, of course. But to just generally answer your question, it's probably more of a 2019 event than it is a 2018 event as we work through the list with each individual customer.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Thank you for that, Brendan. I think we will have time now to take one last question.

Operator

The last question today comes from the line of Ronny Gal from Bernstein.

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

I got 2. The first one I got, COPAXONE for Brendan. Brendan, you've talked about the potential additional pressure coming in from Sandoz. But speaking to payers, it does not seem like anybody is too excited about getting a product from a facility in the [Pearson] when there is like a warning letter every year or so. So the question is, until you get additional competitors, do you really expect that Sandoz product to be a pressure? Or are you assuming there'll be other products coming in before the end of the year? And second, switching over to fremanezumab. I know you heard a lot about this today. Brendan, I understand you got to expect the product approved by the end of the year. But as we think about the payers' cycle of adoption of anti-CGRPs, how late can you be without beginning to see an impact on your final market share? Do you have to be there for the 2020 contracting cycle in early 2019? Or if something happens and you could be a little bit later, do you still you can get to where you need to be on that market share for this product?

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

Yes, so Ronny, and thanks for the question. So let me address the COPAXONE question first. So beyond Sandoz, we don't expect any other generics competitor come into the market for 40-milligram this year. So we're expecting the Sandoz lament their product here in the first half as they've communicated, and we'll see how that shapes. I think we've built that into our plan. If you'd look at the market share that we hold today, about 85%, we will likely see some sharings on price, but I think it'll be right according to what we've planned. In regards to the question on frem, I think

that if we launch in the second half of 2018, we'll be there on time for the 2019 formulary cycle. We've -- payers are aware of where we are. We've -- they've been asking questions. So I think we'll be right in the mix with everybody else. My expectation is that payers will wait until all 3 products are on the market before they make their formulary decisions for '19. And I would expect that because this is a new class of drug, and this is a -- these are new products that most payers will try to take a look at this and give patients and physicians the flexibility to choose what product's right for them. And so hopefully, this is a push towards access for patients.

Kåre Schultz - *Teva Pharmaceutical Industries Limited - President, CEO & Director*

Thank you very much, everybody, for listening in. This concludes our Q&A session, and we look very much forward to talking to you again 3 months from now. Goodbye.

Operator

Thank you very much. That does conclude the conference for today. Thank you for participating. You may all disconnect.
