THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

TEVA.TA - Q2 2018 Teva Pharmaceutical Industries Ltd Earnings Call

EVENT DATE/TIME: AUGUST 02, 2018 / 12:00PM GMT

OVERVIEW:

TEVA reported 2Q18 revenues of $4.7b, GAAP net loss of $176m and GAAP loss per share of $0.24. Co. raised its 2018 non-GAAP EPS guidance to $2.55-2.80.

CORPORATE PARTICIPANTS

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

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

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

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

CONFERENCE CALL PARTICIPANTS

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

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

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

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

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

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

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

Liav Abraham *Citigroup Inc, Research Division - Director*

Umer Raffat *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Teva Pharmaceutical Second Quarter 2018 Financial Results Call. (Operator Instructions) I must advise you, the conference is being recorded today, Thursday, the 2nd of August 2018.

I would now like to turn the conference over to your first 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, Steve, and thank you, everyone, for joining us today to discuss Teva's second quarter 2018 financial results. Earlier this morning, we issued our press release detailing our results for the quarter. A copy of this release as well as a copy of the slides being presented on the 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 second quarter financial results in more detail and discuss additional assumptions around our updated 2018 outlook. Also joining us on the call today is Brendan O'Grady, Teva's Head of North American Commercial.

And with that, I'll turn the call over to Kåre. Kåre, please?

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

Thank you, Kevin. Welcome, everybody, and thanks for your interest in our company. In the second quarter of this year, we had revenues coming out at $4.7 billion, which is very close to our internal expectations. We did see a loss per share in our GAAP accounts that was basically due to some significant write-downs on specific assets from the Actavis acquisition and also a write-down on some of the goodwill from the Rimsa acquisition, but these, of course, were noncash events.

In terms of the non-GAAP EPS, we saw that come out at $0.78, and we are very satisfied with that. And we also saw a free cash flow of USD 0.6 billion, and we are very satisfied with that too. Overall, our restructuring program is well on schedule. Everybody is doing a great job with that, so we are slightly ahead of schedule actually. And you can see that we had a significant spend base reduction of over USD 1 billion since the start of the year when we compare first half of '18 against first half of '17. So I'm very happy about the efforts and the results coming from all parts of the organization on the cost-reduction program.

In the North American generic marketplace, we saw that revenues in the second quarter of '18 compared to the second quarter of '17 were down, and you would say, the 2 main reasons were the competition we're seeing against our generic Concerta where we have more competitors now, and we are seeing decline in sales of our generic Concerta; and then the price erosion that we really saw last year being very strong and, of course, there's a carryover effect of that. And I do think we see a reduction in price erosion and stabilization of the pricing dynamics in the U.S., but it really has not had any major impact in the second quarter.

On our specialty products side, we see very rapid growth of AUSTEDO, growing linearly very nicely. We're very happy about both the growth in number of patients and also about the growth in sales. And COPAXONE, which I'll get back to, has maintained its share in the U.S. in terms of volume, and that's very positive.

We're seeing a very solid performance in Europe. It's fueled by a lot of new product launches, but also by a quite stable situation with regard to both our specialty and generic portfolio in Europe.

All in all, we were able to decrease our net debt by around USD 1 billion, so we're now down to $28.4 billion. As you know, it is our long-term strategy to keep on reducing debt.

I'm happy to inform you that based on the better progress on the restructuring program, but also based on a different low expectation for corporate tax that Mike will get into a little later, we are operating our non-GAAP EPS guidance from a band of $2.40 to $2.65 per share to a of $2.55 to $2.80 per share. And we're also having a minor upgrade of the free cash flow. Now we expect it to come out in the range between USD 3.2 billion and USD 3.4 billion.

Now I said I would get back to COPAXONE, and let me just explain you a little bit about how we see it. You can see here that the revenues in the first and second quarter are pretty similar. We still see a small decline in the second quarter. You can also see that there's a small decline outside of North America and a small decline in North America.

We did get the second competitor in the 40-milligram generic space with Glatopa, which was approved, as you know, earlier in the year. We've seen modest volume share for Glatopa 40 milligram, and we've also seen a relatively stable share for, Mylan increasing slowly, but being sort of around the 15 to 17 percentage points market share.

We have seen a significant reduction from Mylan side recently. As you saw on the WAC price for the generic 40-milligram COPAXONE. And we do expect that, that will, of course, have an effect on the volume, a marginal effect, and also some effect on the pricing. So that's why we still predict in our outlook that there will be a continued downward pressure on our quarterly revenues of COPAXONE in the U.S. There will be a marginally negative down drift outside the U.S., so we are still having a very meaningful turnover altogether this year of more than USD 2 billion, but, of course, it will continue to drag this year and next year as we see more generic competition on the product.

If we switch over to AUSTEDO, then as I told you, we see a very strong linear growth in patients on the product. And this is a combination, as you know, of Huntington's disease, chorea and Huntington's and tardive dyskinesia patients. We see growth in both patient categories, and we see a nice and steady revenue growth. We think this revenue growth will continue, and we maintain the outlook, which is that AUSTEDO, on a yearly basis, in 2018 will do just around USD 200 million.

On fremanezumab, as you all know, we have a PDUFA date set for mid-September, and our API supplier Celltrion has had a combined inspection, which was a PAI inspection for the API for fremanezumab and also reinspection on the warning letter that Celltrion had. The inspection has been completed in July, and we are expecting still to have approval of the product mid-September. And based on getting an approval, we will be ready to launch immediately thereafter.

In Europe, we are hoping to see an approval in the first half of 2019. And there, we will be launching in selected markets all based on the different reimbursement procedures that we have in different markets in Europe.

Now this quarter, I would like to share with you just some brief comments on our strategic principles going forward to give you an idea about how we will be pursuing the business in the future. It's no news that we will work as one company. We have merged specialty generics, OTC, biosimilars, biopharmaceuticals and so on into one organization where we have a classical setup with R&D, manufacturing, global marketing, sales regions, finance and so on. So we have a very classical setup, which we believe we can make more and more efficient over the coming years, basically working on improvement of our margins.

We will be pursuing organic growth. The 2 key elements here are that we'll be building our pipeline steadily, but, of course, relatively slowly because we won't do any big acquisitions of any kind, we won't be buying Phase III products, we won't be buying companies. And the reason why we won't be doing this is because we will be spending our cash flow on a constant reduction of our debt, and I'll get back to some long-term financial targets that also describes this.

Then, of course, we want to maintain our leadership in generics. We want to be both in simple generics, complex generics, injectables, all kind of delivery mechanisms. We want to be first to file, and we also want to be first to launch, and that's, of course, a key element of our business.

In terms of R&D platform, we'll be focusing on biologics, biosimilars, biopharmaceuticals, whatever you want to call it. We have a shared practical platform, you could say, when it comes to pilot scale manufacturing, upscaling, doing large scale clinical testings, manufacturing of finished products, launch and so on. And we have certain therapeutic areas, such as neurology, such as oncology, such as respiratory, where we also have the commercial and medical know-how to pursue innovative biologics and biosimilars.

And then we will have targeted investments. What I mean by that is, it's not like we are stopping investments. For instance, we are building a very nice biologics facility to do large scale manufacturing. We're doing that already. It's included in our cash flow. It's taking place in Germany. We are ensuring that we have all the pilot scale facilities. We've done that in the U.S. We have research facilities around the world that continue to do targeted research. So we will continue to in-license targeted products, but we will not do big scale things, which will be sort of in billion dollars. We will preserve the cash flow for debt reduction.

I won't go into all the details about how we are improving our generics business, but just say that active portfolio selection and management is the key thing. We need to make sure that the products where we are first to file, first to launch are products that are profitable and where we can significantly increase our profitability, so you could say we will be valuing profitability over size. We won't be going for everything. We will be going for what can contribute to our profitability. We will keep TAPI and our OTC products integrated commercially, operationally and that, I'm sure, will increase our margins longer term. The same goes for the profitability focus on pricing. Again, here, both in the pricing dynamics, but also in the efforts of restructuring a whole manufacturing setup, we will be pursuing higher profitability levels, better margins longer term. And in the biosimilars space, of course, also there, we will be targeted and focused only pursuing biosimilars that link into our commercial and medical footprint because we believe that you can only really effectively launch biosimilars if you also have a sort of ongoing commercial presence and medical presence in the areas you're going for.

On the specialty side, of course, we will ensure commercial success of our core assets, such as AUSTEDO, such as AJOVY fremanezumab when we get to launch that. And we will keep on building our own commercial capabilities in those areas and in the different geographies. Fremanezumab will be rolled out worldwide, U.S., Europe, international markets, and we'll be focusing on our internal capabilities in medical, commercial and so on to ensure this.

Also, on the R&D side, we will focus on our current capabilities. We have a wide range of capabilities within biologics and biopharmaceuticals. We have a very well established franchise in the respiratory field. And we have a lot of exciting new projects, which I won't be talking about today, but early-stage things that we think can bring us forward on the longer horizon with a strong pipeline.

But in order to do this in a, you could say, profitable, disciplined way, we have set out some targets that gives you an idea about how we will be looking at our long-term financial performance. We've set out 3 targets: operating income margin, cash-to-earnings and net debt-to-EBITDA.

On the operating income margin, we'll be going for 27%. That's slightly above where we are now. But you have to remember, we are actually under downward pressure right now from the loss of COPAXONE from the pricing pressures we've seen in generics. So we'll probably see that current margin staying below 27% this year, next year, and then we'll help to move it up upwards. And we have a 3- to 5-year ambition to be at or above 27%.

Cash-to-earnings. We need to make sure that every year, we're turning the results into cash, and we don't spend the cash on things that makes the cash leave the cash earnings because we want to pay down debt. So cash-to-earnings, we will aim at being above 80%. And all this, of course, will result in a reduction in debt, and we want our net debt-to-EBITDA to come down below 3x. We think these are very realistic targets. We will be focusing on paying down the debt, and we do not have any plans to raise equity.

This is all I wanted to start out with. I will just sum up briefly. Restructuring program is very well on schedule. The debt is being reduced constantly. Revenue, free cash flow, EPS is on track. COPAXONE maintaining volume share. AUSTEDO growing nicely. We are preparing for fremanezumab for AJOVY. And we've just raised the guidance. So overall, I'm satisfied with the performance in the second quarter.

But now for some more financial details, I'll hand over to Mike, our CFO.

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

Thank you, Kåre. Good morning, good afternoon, everyone. I hope you've had a chance to review our press release we issued this morning. I'd like to take some time now to review the numbers of the quarter and provide you with some more detail on our updated outlook for 2018.

So turning to Slide 14. We start with the review of our GAAP performance. We posted a quarterly GAAP net loss of $176 million and a loss per share on a GAAP basis of $0.24 during the second quarter 2018. As we'll detail on the next slide, the lower GAAP results are mainly driven by impairment charges of $668 million in the quarter.

Turning to our non-GAAP adjustments. The largest were due to impairment of long-lived assets and goodwill, totaling $668 million, comprised mainly of impairment of intangible assets and product rights and in-process R&D assets related to the Actavis Generics acquisition, goodwill impairment related to the Mexican reporting unit, and impairment related to the

(technical difficulty)

impairments. We had an amortization of intangible assets totaling $302 million, which is consistent with prior quarters.

I'd like to point out that $107 million of restructuring expenses were also recorded, mainly pertaining to benefits granted to terminated employees as part of the program announced in December.

And finally, we had an additional contingent consideration charge of $47 million related to our BENDEKA agreement.

So looking at our non-GAAP performance on Slide 16. Revenues for the quarter were $7.4 billion -- or $4.7 billion, a decrease of 18% compared to Q2 of '17. The reduction in sales was mainly related to the continued pressure in North America, with a roughly equal decline in COPAXONE sales and U.S. in generics, which include increased competition to our generic version of Concerta.

We also saw a minor impact of loss of revenues following the divestment of certain products and discontinued business activities. Similarly, the roughly $900 million decrease in gross profit was mainly the result of the sales declines in North American region, which were driven by price impacts, which had a significant negative effect on our gross profit margin.

Despite the aforementioned decline in our gross profit, cost savings from our ongoing restructuring plan and approximately $100 million in other income helped to partially offset the decline in our Q2 operating income.

I will provide some more information on our spend base reduction later in my presentation. Our non-GAAP EPS came in at $0.78, giving us a total of $1.71 for the first half of 2018. Free cash flow was at $600 million for the quarter, a similar level to 2017, but was negatively affected by about $100 million of foreign currency fluctuations. And therefore, our total cash generated for debt paydown was about $0.5 billion in Q2 of 2018.

You can see in Q2 of 2017, we had a lower cash generated because we were still paying dividends, and we had some minor asset acquisitions in 2017's Q2.

Briefly on foreign currency movements, we did see a little bit of weakening of the dollar versus other currencies when you compare Q2 of this year versus Q2 of last year, and that gave us a slight increase of $92 million in the revenue line and roughly $20 million on the profit line. We do expect in the second half the currencies, as the dollar is starting to strengthen, to potentially be a little more of a headwind versus the second half of 2017.

In terms of quarterly revenue on Slide 18. To give you a better view of the positive and negative changes, we have an overall decline of 18% compared to Q2 2017. But looking at the segments and excluding the impact of divestments and other special items, the biggest reduction was in North America, mainly due to the generic competition to COPAXONE as well as a decline in the U.S. generic businesses that I previously mentioned.

In addition, we saw a very low quarter for QVAR due to the timing of wholesale orders following our Q1 launch of the new RediHaler device, and this was offset by the uptick in AUSTEDO and a continuation of the strong performance in our ANDA business.

In Europe, we had a very solid performance mainly due to new generic launches.

In International Markets, our revenues were relatively flat net of the currency exchanges. And the divestments and other is mainly the Women's Health divestments from last year, the closure of the Hungary distribution activities and nonrepeat of the payment of the NINLARO royalties that we had in Q2 of 2017.

Turning to COPAXONE. The quarterly revenues were $626 million, which was consistent with the first quarter. As we go forward to the second half, we expect sales to decline compared to Q2 levels due to the additional pricing pressure and expected uptake of the second generic entrant that Kåre mentioned earlier. We expect for the full year global COPAXONE sales to be roughly $2.1 billion, including $1.5 billion in the United States.

On Slide 20, non-GAAP operating income in the second quarter of 2018 was $1.2 billion, a decrease of 22% compared to the second quarter of 2017. Our European business grew significantly due to the increase in revenues as well as the cost savings from our restructuring program. Our International Markets also benefit mostly from the restructuring savings as sales were relatively flat. And profit in North America was significantly impacted by the revenue decline mentioned earlier, partially offset by the savings in our cost base and some other income for the quarter.

On Slide 21, we're providing our year-to-date achievements in reducing our overall spend base, which totaled a net of $1.1 billion in the first 6 months of 2018. The reductions in the first half were approximately $300 million in sales and marketing, $350 million in R&D, $200 million in the cost of goods line and $100 million in G&A. We also experienced some foreign exchange headwinds, totaling $267 million, which offset most of the reduction in the spend base that we had from divested businesses.

In addition, since Teva's announcement of its restructuring plan, the company has reduced its global headcount by approximately 800 -- or 8,300 employees. As Kåre said before, we're feeling very good regarding the execution of our restructuring plan to date, and we're confident in our ability to reach the reduction of $1.5 billion in 28 (sic) [2018] compared to 2017 year-end's spend base of $16.3 billion.

Furthermore, we're on track to deliver the full reduction target of $3 billion by the end of 2019 versus the 2017 base.

Free cash flow for this quarter was $559 million, which is slightly lower than in Q2 of 2017. When comparing the second quarter free cash flow to the first quarter, please recall that the first quarter figure included significant onetime proceeds from the working capital adjustment with Allergan and the legal settlement with Rimsa as well as lower net CapEx due to the sale of some minor assets.

Turning to Slide 23. We continue to focus on reducing Teva's debt. At the end of second quarter, Teva's net debt fell by approximately $1 billion compared to March 31 to land at $28.4 billion. This was driven by cash generation as well as favorable foreign exchange fluctuations. In addition, we've paid down CHF 300 million bond that was due at the end of July, and we plan to use the current cash balance and future cash flow to continue paying down maturities coming due in the near term.

Our focus continues to be on executing our restructuring plan to free up cash that we can use to rapidly reduce our net debt. Since the start of this year, we've been able to reduce our net debt by over $3 billion. And if we compare today's level to the third quarter of '16 directly following the Actavis/Allergan acquisition, we've reduced our net debt from the peak of $35 billion by nearly $7 billion as of the end of June this year.

So as Kåre mentioned in his opening remarks, we are increasing our full year guidance for the second time this year, including increase in our EPS to a range of $2.55 to $2.80. Our updated guidance reflects higher other income in the second quarter of 2018, accelerated cost reductions from our restructuring plan and a lower tax rate driven by our overall business mix. As we think about the second half of the year, we believe that the single greatest variable on performance will continue to be the impact of generic competition to COPAXONE as well as timing of the generic launches in the U.S.

This concludes my remarks and I'd like to now turn the call back over to the operator to start the question-and-answer session of our call. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) The first question we have today comes from the line of Liav Abraham from Citi.

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

Just a question on COPAXONE. Based on your revised COPAXONE guidance, my understanding is that you're expecting to do about $550 million in the second half in the U.S. versus $940 million in the first half. So that's a decline -- about 40% reduction second half versus first half based on my calculations. Maybe, Mike and Kåre, you can talk -- can you talk a little bit more in detail about what exactly you're expecting for volume and price in the second half versus the first half? And your maybe more specific assumptions on the impact of Mylan's recent pricing action on your net price for the second half and then going into 2019, if possible?

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

Thank you, Liav. This is Kåre Schultz. I will give you a little bit of an overall answer and then we have Brendan here, who is the Head of U.S. and he can further comment on it. So first of all, we have to acknowledge the fact that it's hard to predict precisely generic erosion curves on original products, how they sort of lose out in volumes to generics these days. There's been a lot of changing dynamics in the marketplace. And for that

reason, it's difficult to predict. And COPAXONE is difficult to predict, and I've been in situations in previous companies with other products that have also been difficult to predict. So when we give our guidance, of course, we need to take everything into consideration. And as you can see, we've been holding on to roughly 85% of the volume in the first and the second quarter of this year. But we do think that's a very high level, and we are seeing probably right now that we have slightly less maybe 83% of the volume. So we are expecting that the fact that we have 2 generic competitors will lead to some reduction of the volume. And then, of course, in terms of price, that's a complicated game where we have a lot of different contracts that we're negotiating and then that could also be some impact there. But you have to, I would say, have the facts from us that we don't know how this is going to play out exactly. Of course, we can't know. So there's always an uncertainty on this, and that's also why we have the range on our earnings per share because it could go -- data could go worse. But we think we're taking a prudent approach and coming out with a guidance that is very, very realistic. But maybe, Brendan, you have some further comments?

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

Yes, thanks, Kåre. So I think if you look at the impact on the market, I think that the market has somewhat overreacted to the WAC price drop by Mylan. I think that the -- probably even net price, their selling hasn't changed all that much. They've just lowered the gross to net. And that's not something that was completely unexpected. If you think about when Momenta or Sandoz would come in stronger with our product originally, we had thought it would be April, then we would -- thought it would be July. And they're still trying to build towards that. So when that event happen, we predict there would be more price competition. And as Kåre said, we had planned for some continued mild erosion in both volume as well as price. So I think the $600 million for the second half of the year is certainly doable, and I think the $1.5 billion is -- we're on target for that.

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

Maybe just a quick follow-up. You kept your revenue guidance flat, but you've increased your COPAXONE guidance for the full year. So what is -- where are you expecting things to get a little worse than your expectations at your Q1 earnings?

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

Yes. So, Liav, I'll take that one. We're seeing a couple of things as we go into the second half. COPAXONE has come up for the full year, and we did raise the revenue a little bit in the first quarter. We're having -- and as we go into the second half, we do actually see some currency headwinds. So we are going to see a decline in the the dollar-based sales for the nondollar regions, Europe and International Markets. We're also seeing a little bit of headwinds in the U.S. generics and some assets like QVAR, which is a little bit lower than we originally expected. So overall, we see revenues still coming in relatively in line, but we're going to have a little bit more profitability, and that's why we've raised the EPS and the cash flow.

Operator

The next question today comes from the line of David Maris from Wells Fargo.

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

A couple of questions. First, Kåre, you mentioned that you're seeing an improved U.S. generic pricing dynamic, but you're not experiencing it yet. So can you kind of explain to us that nuance? And I would suspect that Teva is representative of the market. So where are you seeing it? And should that continue through the year? Or is it something that you think might just be temporary? And then second, can you explain a bit how the long-term targets you've provided today differ from the ones that you used at your previous firm and why not a return on invested capital target?

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

So thanks for those 2 questions, David. So first on the generic pricing. The way it works is, of course, that on a day-to-day basis, there's all kind of requests for proposal on this, that and the other product. There's all kind of pricing discussions with customers on thousands and thousands of products. And our assessment of that is not precisely identical with the market because we don't have full insight into the market. But based on what we're seeing in the second quarter, we believe that there's an improved pricing dynamic on U.S. generics. That being said, of course, the actual sales you have are also very much affected by the launches you have and by competition on volume. And as I said in the beginning, we have seen a strong volume competition pickup on Concerta because there's been other generics to Concerta being launched and, therefore, we're losing sales on Concerta. So that is really nothing to do with the pricing, that's more the effect of more approvals coming in. And we've had relatively few new launches in Q2 than we had in Q1, and that also affects the sales, of course. So I cannot give you any firm conclusion on whether this improved pricing dynamic will continue or whether it's just a reaction to the very, very bad pricing dynamics in the third and fourth quarter of last year, and it's going to come back. I don't think it will come back. I think we will see a more, I would call, mature and sensible market where we have a more stable situation now with 3 big buyers and a number of manufacturers, of course. So I think we have reached a new level of generic pricing, which is actually pretty close to the European level now. So at least when you discuss drug pricing, you can't say that U.S. generics are more expensive than elsewhere in the world on average. And that is also an indication for us reaching a level of stabilization. Then if I can just jump to the other question, which is the long-term financial targets, then I would say, there's a big similarity between these targets and targets that I said when I was in my previous job as CEO of Lundbeck. And it's basically because it matters that you generate cash whether you use it to pay to your debt investors, which is what we have here because we have so much debt or whether you use it to pay to your shareholders because you don't have debt and you return money to the shareholders. It doesn't really change your target for the cash you want to have, the cash of earnings that you need. And in the case here in Teva, we simply have too much debt, so we need to have a target of bringing down the debt. And you can only do that if you have a good cash-to-earnings ratio, and you can only generate cash and earnings if you have a good margin, and that's why we're setting the margin target of 27%. And I think that's in line with what a mixed company like ours with the product portfolio we have can reasonably be expected to achieve in a 3- to 5-year time scale. And of course, this is not the end of the road. I mean, we would like to do even better, but as you also know, it's my policy that you set targets and then you don't discuss new targets before you reach them. So we've set these 3 targets. We will reach these 3 targets within the next 3 to 5 years. Once we reach them, we'll set new targets for the future periods.

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*

Kåre, if sales stay at $17 billion to $18 billion, your longer-term guidance for operating margins basically imply the EBITDA at $5.2 billion to $5.5 billion; $5.2 billion is what you've sort of guided to this year, which is basically not much growth. You had -- you and Kåre had talked about returning the business to growth post the trough. So I'm wondering if you could talk about that. Secondly, what are your assumptions for net debt by year-end and your level of debt paydown this year, next year? You had talked about potentially selling Medis. I don't know where that is in the discussions. And then lastly, Brendan, if you can just give us a little bit of color on ANDA approvals. I know there hasn't been much, but what are you expecting? What's going on -- what do you think is going on with the FDA? What can we expect for the back half of the year?

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

Okay. Thank you, Jami. You elegantly managed to squeeze in 3 questions, which we will answer. I'll take the first one, then Mike will take the one on the debt and then Brendan will comment on ANDA. You're absolutely right that the run rate right now is probably for next year something around $18 billion, and that gives the EBITDA you're talking about. But that's just for next year. And next year, as I've said before, that is, hopefully, the sort of a valley -- the bottom of a valley because, in September, we very much expect and hope to get the approval for AJOVY, and we think that, that's a fantastic market. The migraine market is very, very promising. We think there's enormous unmet need. So with a good launch of AJOVY, that sales will start to accumulate in '19 and will be meaningful in 2020. Same thing for AUSTEDO. We expect to continue to grow our sales. Same thing for our respiratory and eConnected respiratory that we are expecting to bring to the market next year. So we're really seeing a situation where

next year is a real tough restructuring year still, with COPAXONE sales coming down, with continued pressure on different parts of the business. But then based on good launches, based on good portfolio optimization of our generic business, we hope to see growth coming back in 2020. And then maintaining the margins, of course, we do expect to see by then a growing EBITDA. But the reduction of the debt is really not hinging on strong growth of the EBITDA. We will reduce the nominal debt, no matter what. So that's not -- that's one long-term target is really not hinging on that. But, of course, the long-term projection for earnings is very much linked to us being able to start growing the top line again once we get to 2020. So that was the first question. And then I'll turn over to Mike on the debt question.

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

Yes. So we've reported this quarter the $28.4 billion in net debt. If you look at the remainder of the free cash flow to go, you'd end up, depending on where currency goes, somewhere between $27.5 billion and $28 billion, depending on exchange rates. For next year, we are still looking at a couple of assets that were in potential divestment. It's the Medis, it's a small asset here in Israel and a little OTC business in the U.S. So all in all, with that and free cash flow, we hope to be able to pay down anywhere from $2.5 billion to $3 billion again next year. And then as we go forward, we're still targeting to get at 4x by the end of 2020. Of course, that will depend on how we do in growing the revenue after 2019, as Kåre just discussed. So we're still focusing all of our efforts in terms of generating cash and paying down debt. We've been very successful so far in the last 8 quarters. We've paid down $7 billion. We want to continue to pay down. And we won't be able to match that pace necessarily going forward, but we will continue to generate cash and pay down debt. Brendan, I think you had the third part of the question?

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

I did. Jami, so your question was around ANDA approvals and what's going on with the FDA. And it's, obviously, hard to speculate what is transpiring with the FDA. We came out of the gates pretty fast in the first quarter. We had 10 launches in Q1 .And so far -- and then 1 in Q2 and then so far 1 in Q3. So we expect throughout the remainder of the year that as we work through some of our different ANDA files with the FDA, we still have 10 to maybe 15 launches between now and the end of the year. So we'll see that number should start to tick up as we get into the second half.

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

Okay. Can I ask a follow-up question, Kåre? Can I ask a follow-up question?

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

Yes, quick one.

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

Okay. The $18 billion that you talked about next year, is that -- do you think that is a trough sales number?

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

Yes, that's what I tried to explain that I think that we are probably hitting the bottom of a valley or a trough, whatever you want to call it, in '19. And then based on the dynamics that COPAXONE is not dropping so much anymore because it's -- a big chunk of it is gone by then. And that AJOVY is picking up, AUSTEDO is picking up and I expect this to see a positive momentum on sales from 2020.

Operator

The next question today comes from the line of Chris Scott from JPMorgan.

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

Kåre, I'm sure you handle around how we think about the -- first of all, appreciate the 27% margin target, but just how the P&L evolves over time? So I guess, 2 questions. One, with your gross margins, is there further manufacturing efficiencies from some of the efforts you're making beyond 2019? Or is the $3 billion expense kind of reduction capture a lot of that opportunity? So when we get kind of gross margins next year, is that a decent run rate? And then second question on longer-term plan. When you figure out some of these R&D initiatives, whether it is biosimilars on the branded business, et cetera, can you do that within the existing $1 billion run rate R&D budget? Or do we have to think about spend starting to increase over time as you start on some of those projects?

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

Okay. Thank you, Chris, for those very interesting questions. So if we think about the margin overall and what can be done, you could say, longer term after 2019, then first of all, we have to realize that, in '19, there's continued pressure on the margin from the fact that COPAXONE is reducing in sales and the fact that we don't really see meaningful big sales of AJOVY yet coming in compensating for that. But, of course, longer term, there's a better gross margin on AJOVY and on AUSTEDO than there is on the bulk of our business. So longer term, that will sort of affect the margin in a positive way. In terms of our gross margin, then, of course, long term, there will continue to be possibilities for optimization. And it really comes from 2 places. It comes from the manufacturing cost, that's a long-term game where you consolidate, you improve your way of running things, you mature, you move products to the right plant, you shut down plants that are no longer efficient or needed. And in doing so, you can gradually improve your gross margin. But it also comes from the portfolio management. If you manage your portfolio of products geographically and your portfolio of generics in each of the key markets and you manage the pricing of those products in a very good interactive way, then you also, of course, by improving the pricing environment improve your gross margin because it's both the manufacturing cost, but it is also the average pricing that goes into this calculation. I'm convinced that we, as the biggest generic supplier worldwide, will be able to continuously optimize our skills in that area, both on the manufacturing side and on the pricing dynamics side. But it's not a big splash like the $3 billion that we are cutting out of cost right now. It's more gradual, but it will, of course, be our ambition to getting more efficient as we go forward and, therefore, also, after 2019, continue to see improvements on the gross margin, but not as big as the ones you're seeing now. You have to remember what we're doing right now is really to offset the loss of COPAXONE, we're cutting out $3 billion basically to compensate for the loss of revenue in the sort of order of magnitude of $3 billion. But we will continue to improve, and we will continue to work on getting the gross margins improved also after 2019.

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

Chris, you had one more, and if the $1 billion run rate is enough to support the biosimilars?

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

Yes. And I should have answered that explicitly. It is enough, yes, it is.

Operator

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

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

A couple of questions. The first, Kåre, for you. You're talking about saying basically all the operating lines of Teva, all the away from novel biologics to OTC to commodity broad line generics. It seems like you're taking on a lot, and the question is as you're trying to narrow the focus and execute better, is there no room to think about stepping out of some of those lines? And you've never made your own biologics. And you need some basic art to actually develop novel medicine. Is this just kind of a temporary thing? Are you just going to do what was done before, just better? Or are

you still going to take a further look at participation on those product lines before this essentially commitment to stay in this? And second for Brendan on fremanezumab. It's more of a commercial question. I'm seeing Amgen right now going and going very hard for share by giving the product for free for a while. And when I think what you'll have to do as the second or third entrant is essentially to do the same in order not to fall behind on share before the payers begin to narrow their access in 2020, 2021? Should we think about the first kind of, call it, half year of fremanezumab in the market as essentially be a period when you're largely giving the product away in United States to capture a significant market share to be competitive when it comes to payers? And none of you guys have mentioned it, so I'm going to sneak kind of 2.5 questions here. You haven't mentioned the OAI status of that facility. Is that going to be official move? Or is there a strong assumption that will happen and why?

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

Which facility, Ronny?

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

The one -- the Celltrion facility that make fremanezumab.

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

Thank you very much. I'll answer the first one and your half question as well, and then Brendan will comment on fremanezumab in the marketplace. So you're correct that we're combining, you could say, all the revenue lines per market in order to optimize the profitability. We need the profitability, basically, to generate the cash to pay down the debt. So we are going to sell off any chunks of the business. We're going to integrate it, make sure that we get the scale benefits of having one back office organization, having a well structured sales force and just basically optimizing the revenues, reducing the cost, making sure we generate the cash flow. Now then when it gets to the R&D piece, we do actually have which -- I was actually also surprised when I joined the company, we do have excellent discovery research going on also in biologics. We have activities in the U.S. East Coast, the U.S. West Coast, in Australia, in Europe. So we have activities in biologics in many places. And even though we have not sort of launched a fully homegrown biologics or biopharmaceutical, we have actually done all the bits and pieces, and we've taken products that are biologics through basically all the different steps, whether it's the early steps or the late steps. And we are expanding and have expanded our capabilities, both in the development space in terms of pilot scale facilities, everything you need. And also in the disease understanding, we do believe that when we talk about respiratory, when we talk about neurology, CNS, and when we talk about oncology, we do have internal experts who knows what they're talking about. And we do have a chance of commercializing competitively because we have been commercializing in these areas for the last 10, 20 years. So that's really the thinking behind it, that we do think we have a good pace there. And we know that we are not the leaders in biopharmaceuticals, we are not the leaders in biosimilars, but we are reasonably good player, and we have some reasonably good medical and commercial footholds that, we think, we can utilize to generate a really nice business base on these assets. Then I'll also answer your half question on the Celltrion thing. What I tried to say in my opening remarks was that there has been an inspection which was a combined PAI and reinspection of Celltrion based on the warning letter and based on our fremanezumab filing, and that inspection has taken place, and we are satisfied with the outcome. And we still expect to get the approval mid-September, but, of course, this is FDA, so nobody can give any guarantees or promise anything, but that's what we are hoping for and that's what we're planning for. And then that leads into your second or third question on the commercialization of fremanezumab, and I'll hand that over to Brendan.

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

Ronny, the question on the frem and how the migraine market is going to evolve, so I think it depends on when you launch the product as you look at '18. So I don't know that it really matters whether you are second or third to market because those products will be very close. Most of the payers right now are blocking Amgen's products. So it's difficult to get reimbursement as they're looking at this market to form. So we're in conversations with the payers already for 2019. I'm sure, Lilly is the same and, obviously, Amgen as well. So I think their 6-month period is largely a reflection of when they launched. We launch in late September. If we launch in late September, then I don't think we have quite that long of a runway till the January formulary starts. So I don't know that I would think about frem as a 6-month period where we largely give away product.

But I would think that all of the products will have either some kind of free product sampling program for a couple of months so that they can work through the insurance coverage issues. But we believe that we'll be competitive there, we're confident in the molecule, we think it's a very good molecule, we think we've got a very good package that we put together. So we're looking forward to the launch, looking forward to competing and think this is a really good space to be.

Operator

Next question today comes from the line of Greg Gilbert from Deutsche Bank.

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

Two strategic ones for you, Kåre. First, when you look at the limited uptake of generic COPAXONE for the generic players and the limited uptake of biosimilar Remicade for those players, does this trouble you at all in terms of the differentiated generic products you have in your portfolio and/or the biosimilars that you eventually hope to launch? Do you think the system needs to change or rebates need to go away? Just trying to understand the rationale to make significant investments in these types of products if generic COPAXONE and biosimilar Remicade are sort of telling at all. And number two, in your generic industry or your generic strategy slide, you talked about the importance of API and OTC, but you did not mention, I don't think, distribution even though you own a unique distribution asset. Does that mean you don't see that as an important differentiator between yourselves and other manufacturers? And if not, why not sell it if you could get a sort of leverage-enhancing price for it?

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

Thank you, Greg, for 2 very interesting questions. So the first question around what is the chance really for getting meaningful profitability out of biologics or in biosimilars. And my experience is that you can actually compete very well in, you could say, the branded generics, biosimilars space. And this is something you can see in diabetes. You can see -- I know it's 505(b)s they are called, I guess. So it's not straight out biosimilars, but it's really the same. And you can -- you've also seen it in the growth hormone space. But there's a very specific thing you need to be aware of in order to compete, and that is, if you really want to make a good profitability out of it, you should not really just compete on price. You need to have the commercial setup already in place, so you know the key opinion leaders, they trust in your new product, you know the patients, you have patient support programs and so on. So you can't just launch a biosimilar like you launch a generic and then hope to get share by just having the pharmacies switch the patients. That's not going to work. You need some kind of commercial backbone. But that also means that if you want to be successful, you should probably not do what Mylan is doing, just taking down the price because you need to have a reasonable price to get back your investments and to protect the patient support, the sales force that's really needed to gain volume share in these areas. So I really personally believe I know how to do this. I'm sure, together with the U.S. sales and marketing organization, we will know how to do it. And we're going to prove it with the biosimilars that we're going to be launching that we have in-license from Celltrion. So that was the answer to that question. On the ANDA side, I would say that I do see ANDA as a strategically important asset to us because they are in distribution, they are the biggest secondary distributor, but maybe, Brendan, you can also give it a few comments.

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

Yes. So I do think that the ANDA business is a differentiator for us. I think it's a -- something that keeps coming up in the marketplace. It gives us a strategic advantage. And we look forward to continuing to grow that business. The performance for the first couple of quarters has been pretty strong. It was fueled by a strong flu season in Q1, and that has spilled over to Q2. It's a very opportunistic business so it ebbs and flows. But I think it is a solid asset that we want to continue to maintain and optimize.

Operator

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

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

I had 2, if I may. First, on generics, it seems like your gross margin in the U.S., excluding COPAXONE, dropped from 48% in Q1 to 43% in Q2. I just wanted to understand the dynamic there, what's driving that. It's clearly generics, but just what's specifically within that? And secondly, on CGRP, you mentioned that inspections happened and you also mentioned you're satisfied with the outcomes. So my question is, can you give us some more color on whether or not you've got any feedback from FDA that makes you feel more satisfied?

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

So thank you very much, Umer. Mike will give you the answer on the gross margin first and then I'll take the other question after that.

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

Yes. So there's a couple factors in the gross margin in North America that you're looking at in the press release. COPAXONE was relatively stable, but you saw our QVAR was down. That's a high-margin product. In terms of the generics, we did see a little bit of a mix change, so that you're having a little bit lower margin in there. You're also having a little bit of some recalls that we did on some minor products affecting that gross margin. So overall, that's probably closer to a more forward-looking run rate that you're going to see in there because we had an exceptionally strong quarter in Q1 in terms of mix and now we're getting back to a more of a normalized for the rest of the year.

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

And in terms of the inspection at Celltrion, I can't really give you any specifics on it, and it's not because we are in any extraordinary dialogue with the FDA. We are in the normal dialogue that you have approaching your PDUFA date. But we are still optimistic of achieving the approval on the PDUFA date mid-September.

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*

First question for Brendan. Can you give us a sense where you are in terms of the portfolio optimization process within the U.S. generic business? And specifically, I asked the question because last couple of quarters, you talked about basically holding on to roughly 15% share of the U.S. market and that's started to slip a little bit, I guess, in the last couple of months. But if I think about other companies, they have gone through similar processes. They've taken about 2 years to play out. And there's been pretty significant reductions in their unit market share even though dollars have held in. And I just sort of question how should we be thinking about Teva's market share on a unit versus dollar basis. I mean, should we be surprised if market share falls to 10% or 11%? Or is that sort of realistic given, I guess, the process that's in place? And follow-up question for Kåre, specifically, on your BD commentary early in the call. I think I understand the gist of it, companies are not going to be spending large sums on revenue-generating assets companies or overvalued public biotechniques, but how do we think about in-license strategies around earlier or later-stage assets in terms of sort of building potential growth profile post 2020? I mean, would we -- should we be surprised to see the company do biobucks deals for Phase III assets? Or do you think that even those types of structure, frankly, are just kind of overpriced in the current environment and you're going to be looking at more sort of Phase IIa, Phase IIb-type deals?

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

I'll take the first question here around the market share and the portfolio optimization process. So we've largely completed that exercise with most of the customers, so I would call that complete. And as we've said before, about 20% of the products we got price increases on, but about 80% of the products we'll rationalize and they'll move to other suppliers. But that's not an immediate exercise. In some cases, they had inventories, we had API, we had inventories. So that, to your point, it will bleed out over the first 2 quarters and maybe a couple in the coming quarters, so really won't be visible probably until Q3 or Q4. But as we do that, we're also launching new products. And many of the products that we rationalized, we had very low market share anyway. So I don't think that you'll see really a big change in our market share. There may be a 1 percentage point fluctuation or so, but I don't think you're going to see a big phase in the market share based upon mix and based upon how it's playing out. So that would be my answer there.

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

So Elliot, I'll give you a comment on the BD question. Very good question. So the idea is to develop the portfolio, I would call it, organically, which basically means that, of course, we need to do in-licensing, but we will do it early. So basically, we will not in-license Phase III assets, we will not acquire companies with assets in Phase III or just about to go into the marketplace. We will look at things that are preclinical, Phase I, maybe early Phase II. That means that the upfronts will be limited and that we will only be sort of accumulating financial liabilities on part of those acquisitions as we see success with the pipeline. So this is a longer-term strategy. It takes, of course, longer than it takes if you're buying stuff very late. But it's also -- you should see it as this a strategy where the new biologics pipeline will start to come to the marketplace maybe 5, 6 years from now with the first assets. So it's not something that's going to change our growth pattern for the next 2 to 5 years. But it will, of course, preserve cash to reduce the debt.

Operator

The last question today comes from the line of Irina Koffler for Mizuho.

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

I was wondering if you could provide an update on your fremanezumab data because of the recent positive results out at Pfizer. And then the other question I had was on your retained earnings for the end of 2018. Do you expect that to be negative? And do you expect to pay your convertible bondholders in company's stock rather than dividend?

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

Irina, thank you very much for those 2 questions. I'll take the first one and then Mike will take the second one. So with regard to Fasinumab, we don't really have any comments to the Pfizer Lilly results. You could say that the situation is basically unchanged in the sense that there's an enormous unmet need for nonopioid therapy for pain in this patient group. There's a clear-cut efficacy on Fasinumab and also on the Pfizer Lilly drug. And there is a safety issue that has been followed for many years by now where there is still no real clarification. So we are, of course, hoping that the longer-term trials, both the ones that we are conducting or rather we are conducting together with Regeneron, will come out with positive results, but we don't know. And I'm sure that Pfizer Lilly, they're holding the same for their longer-term studies that they also come out positive in terms of safety, but it's really too early to say. So I think that with our partner Regeneron, we are pursuing this. They're doing a great job on it and, of course, we hope for positive results. But being Phase III safety results, you never know until you have the real data. And we don't have that as of now.

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

Yes, thanks, Kåre. And Irina, on the retained earnings, we do expect to convert the mandatory convertible preferred shares into stock, and that's been included in the share count that we've used for the updated EPS guidance. So that's our view for now, and that's what's most likely to happen.

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

Thank you very much for listening into this call, and have a nice day.

Operator

Thank you very much. That does conclude the conference for today. For those of you wishing to review this conference, the replay facility can be accessed by dialing +44-3-333-009-785. The reservation number is 6984104. Thanks for participating. You may all disconnect.
