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# Teva Pharmaceutical Industries Ltd.

(TEVA)

Q4 2018 Earnings Call


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# MANAGEMENT DISCUSSION SECTION

**Operator:** Good afternoon, ladies and gentlemen, and thank you for standing by. Welcome to today's Teva Pharmaceutical Industries Limited fourth quarter 2018 results conference call.

At this time, all parties have been set in listen-only mode. There will be a presentation followed by a question-and-answer session. [Operator Instructions]

I must remind you that this conference is being recorded today, Wednesday, February 13, 2019. And I would now like to hand the conference over to your first speaker today, Mr. Kevin Mannix, Senior Vice President, Investor Relations. Please go ahead.

## Kevin C. Mannix

*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*

Thank you, operator. And thank you, everyone, for joining us today to discuss Teva's fourth quarter and full year 2018 financial results. We hope you've had an opportunity to review our earnings press release, which was issued earlier this morning. A copy of this press release as well as a copy of the slides being presented on this call can be found on our website at www.tevapharm.com, as well as through our Teva Investor Relations app.

Please note that the discussion on today's call 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 and facilitates analysis by investors in evaluating the company's financial performance, results of operations, and trends. A reconciliation of GAAP to non-GAAP measures is available in our earnings release and in today's presentation.

To begin today's call, Kåre Schultz, Teva's Chief Executive Officer, will provide an overview of the 2018 performance, recent events, and priorities going forward. Our Chief Financial Officer, Mike McClellan will follow by reviewing the fourth quarter financial results in more detail before providing an overview of Teva's 2019 financial outlook.

Joining Kåre and Mike on the call today is Brendan O'Grady, Teva's Head of North America Commercial, who will be available during the question and answer session that will follow the presentation. Please note that today's earnings call will run approximately one hour.

And with that, I'll now turn the call over to Kåre. Kåre, if you would, please.

## Kåre Schultz

*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

Welcome, everybody, and thanks for listening in. In 2018, we did meet or exceed all the components of our 2018 financial guidance. This meant that our revenues came in at $18.9 billion. And we did see a stabilization of the quarterly sales between the third and the fourth quarter.


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Our non-GAAP EPS came out at $2.92 versus the original guidance, which was significantly lower. The free cash flow also met the guidance and came in at $3.7 billion. And as you all know, it's important that we keep generating cash in order to serve the debt that is still significant.

We deployed a new and unified and simplified organizational structure as a way to reduce the spend base and still keep a very efficient commercial organization, manufacturing organization, and R&D organization. We did see a reduction of the spend base of $2.2 billion in 2018. And we also saw a reduction of the net debt by 14%, down to $27.1 billion.

In the United States, we launched AJOVY. We had approval, we had launch, and we're seeing a very, very strong development in the marketplace that we are very satisfied with.

We're also seeing continued strong growth of AUSTEDO, the drug that's been used in Huntington's disease and tardive dyskinesia. And it continues to gain momentum quarter by quarter.

On COPAXONE, we did see a decline, as expected. But we are maintaining a high volume share in the U.S. and European markets.

And in the North American generic market, we did see revenue stabilizing, which is significant since we have had a significant decline in the overall North American generic market over the last five years. And we talked about this already after the third quarter that we were seeing a stabilization. I mentioned it in January at JPMorgan. And I can confirm it again today, that we are seeing stabilization in the total revenues at around the level of roughly US$1 billion per quarter for our North American generic revenues.

If we take a look at the spend base. Then you probably all remember that a bit more than a year ago when we announced the restructuring plan, we made it very simplistic. We said what was the total spend we had in 2017? We are going to reduce that with $3 billion. And we will do it no matter what happens to exchange rates, comparatives, all kind of details. So make it simple.

Now we're well on the way to do that. We had a gross reduction of $2.3 billion and then we had $0.1 billion of foreign exchange headwind. But as I said, no matter what the exchange rates are, we will meet the target and reduce the spend base in 2019 by $3 billion.

This of course has not come easy. I already mentioned the One Teva plan, where we're unifying all our different functions into a classical functional organization. As a consequence of this, we've been able to reduce the total manning of the company by more than 10,000 employees since we started the restructuring plan.

We've also been reducing the manufacturing footprint. And in 2018 we have been closing seven manufacturing facilities and 11 more will be closed or divested in 2019.

If we take a look at the net debt, there's been a couple of significant movements. First of all, as you probably remember, last spring we did a new issuance. We used the proceeds from the new issuance and from our cash flow to pay down all term loans, meaning that we don't have any term loans, any bank loans right now. And we also moved some of the bonds into a longer maturity. The net effect of all of this was a reduction of the debt by $4.4 billion.

If we now turn to, you could say, the future growth drivers, then AJOVY is, of course, a key driver. As you all know, AJOVY is a drug in a new class of drugs that treat chronic migraine with a fantastic clinical efficacy,


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basically reducing the number of migraine days on average of 50%, in some cases up to 75% to 100% reduction of migraine days. So this is a really a fantastic offering to patients. First time in 20 years that there's a real new therapy for migraine.

We are in this class together with two competitors. And we are very satisfied with the patient capture we see. We see that we roughly now capture around 30% of new to brand patients. And we hope of course to be able to maintain this level going forward.

A lot of new prescribers are coming every month. And we expect to grow the prescriber base on a steady basis over the coming years. So AJOVY's very important for our future growth. And we are very optimistic about the outlook.

Another strong driver is AUSTEDO. And as I said, it's having a high market share in Huntington's disease, in movement disorders in Huntington's. But it's also growing strongly in tardive dyskinesia. We have one competitor that's also in tardive dyskinesia. And this is a new market where there's basically been really no therapy approved before AUSTEDO and the competing product.

So here we are sort of opening up a new market. And it's a big market. Probably 0.5 million people in the U.S. suffer from tardive dyskinesia. So we do expect the patient numbers to keep on growing over many years. And as a consequence of this, we do expect of course also that the revenues of AUSTEDO will keep on growing. In 2018, we exceeded the target we had of $200 million. And we expect this of course to keep growing going forward.

If we move to the drag we've had on our revenues for the last year, then all of you know that it's COPAXONE that's the key drag. And that the drag is coming due to the expiry of the patent and the fact that we have generic competition both on the 20 [milligrams], since a couple years, and now also on the 40-milligram.

If you look at the TRx count, you will see that on a sort of moving annual total, we're probably losing around 20% of the scripts. And if you look at the revenue, you can then deduct that we're probably losing on pricing something in the ballpark of 25%. Altogether around 45% on an ongoing basis.

We expect this to continue at a similar level during 2019. And as a consequence of that, we will of course have a reduction in revenue on COPAXONE.

It's important to say that outside of the U.S., we have a more stable situation. We do have a modest decline in Europe. But it's a lot less than what we're seeing in the U.S. And we're very happy to conclude that we still, at the end of the year, had something like 75% volume share. Of course this will be somewhat reduced during 2019 and again in 2020.

If we look at our focus areas, then a key focus is of course to secure the revenue generation. I just explained about AJOVY and AUSTEDO. And we have of course not removed the resources during the reorganization from those products, which is probably why they are doing so well in the marketplace.

It's also important to mention that we are also going to launch AJOVY in Europe. And that we are also working on broadening the geographical base for AUSTEDO. And I think I'll just mention here, talking about Europe, that worth mentioning is where we've had a lot of headwinds in the U.S. the last couple years on COPAXONE and generics, actually Europe had its best year ever in terms of operating profit for Teva in 2018.


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We are seeing a stabilization of the generic business. But of course, as always, it only stabilizes as long as you execute new launches that offset the price loss you have on old products. But that's what we're seeing right now and what we are striving to maintain.

We continue to have a drag on revenue from COPAXONE and from the ProAir HFA franchise, where we do see also as generics being launched.

On the expense side, we will have to keep on reducing our total spend. That's why we are having plans to meet the target of a $3 billion reduction versus 2017. We continue to consolidate our manufacturing sites by closing and divesting some sites and moving production to other sites that continue to be in operation. We do have a lot of sites.

And we also have sometimes challenges with GMP inspections and making sure that we have perfect compliance and quality, which is of course what we strive for. Right now, we have had an inspection last year in a site in Florida, Davie, where we recently got a warning letter, which was expected. And we're working to rectify it. And we don't see it having any short term negative effect on our business.

We are targeting investments in our pipeline. We are targeting investments in biopharmaceuticals and biosimilars. And we are constantly optimizing our portfolio of both generic and innovative development projects.

On the debt side, we're committed to utilizing our cash to pay down debt and to continue to do so over the coming years. We have $1.7 billion that's scheduled for repayment in 2019. And we will have no liquidity issues with paying down that debt as we will also not have in the coming years.

So basically, we have a financial outlook that is completely in line with the overall plan that we created more than a year ago. This is a trough year, as we have been saying for, yeah, well, since the beginning of the plan. This is the year where we bottom out on revenue and operating profit. And in 2020, we expect to return to growth and continue to do so in the coming years based on the launches of the new products.

We have set out three long-term financial targets. And I'd like to explain just briefly why these are the most important targets for the successful financial performance of our company.

First of all, we need to generate solid earnings on a long term basis. And the only way to do that is to have a strong operating income margin. Right now we are below the 27%. But in the coming years, we will be improving it. It's a combination of improving, you could say, manufacturing costs for generics by optimizing our manufacturing base, and getting the margin lift from launching new and innovative products that typically have a higher margin than generics.

When we then generate the income, we need a high level of cash-to-earnings in order to have the cash to honor our debt. That's why the cash-to-earnings needs to be above 80%, which we will ensure in the coming years. And of course one of the ways you ensure that is that you don't go out and buy a lot of stuff, a lot of things, a lot of companies. We'll be focused on optimizing our own business rather than adding new businesses to it.

And as a consequence of these two targets, we will be able to reduce our net debt. And we do have a target here that we will have a net debt which will be below 3 times EBITDA. And we expect to reach that within these three to five years.

It goes without saying that we are committed to pay down the debt. And we do not have any plans to raise equity.


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Now having talked about the financial targets, I will now hand over to our CFO, Mike McClellan.

## Michael McClellan

*Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.*

Thank you, Kåre, and good morning to everyone. I will now take you through a summary of the Q4, a brief snapshot on the 2018 results, and then follow with our 2019 guidance and some important assumptions there.

We start with a review of our GAAP performance. We posted a quarterly GAAP net loss of approximately $2.9 billion and a loss per share on a GAAP basis of $2.85 for the fourth quarter 2018. As I'll detail in the following slides, the GAAP results were impacted mainly by impairment charges and recurring amortization.

So if we turn to the next slide, you can see here our non-GAAP adjustments. In Q4 we saw significant goodwill and intangible impairments of approximately $2.7 billion, mainly related to the international markets, coming from a decline in value, driven by currency declines as well as negative trends in Japan, Russia, and Mexico.

Also we see other impairments of approximately $1 billion. A large percentage of this is tied to – also to Japan, related to our Takayama plant and our long listed products.

We also have seen a revaluation of intangibles in international markets, U.S. and EU, primarily from the Actavis acquisition. Restructuring charges of $46 million in the quarter were significantly lower than the first three quarters of 2018, as a majority of the actions have already been recorded.

So looking at our non-GAAP performance on slide 15. Quarterly revenues were $4.6 billion, a decrease of 16% compared to Q4 2017. That decrease was mainly attributable to generic competition to COPAXONE in the U.S., declines in U.S. generic products, and business divestments of approximately $140 million, the majority which pertain to the women's health. And the remaining was a distribution business in Europe.

This was partially offset by new launches in the U.S., mainly generic Sensipar and Cialis, as well as our brand AUSTEDO and our Anda business.

Compared to Q4 2017, we experienced a negative FX impact of $100 million quarter-on-quarter. Net of the FX, revenues in Q4 2018 decreased 14%.

Gross margin was 51.1%, compared to 50.9% in Q4 2017. The change in gross margin was driven by an increase in our European Generics profitability, the discontinuation of our OTC JV with Procter & Gamble, and higher contribution from new generic launches in North America. This was partially offset by the decline in share and profit of COPAXONE and various specialty products in U.S., as well as the divestiture of our women's health business, which had a higher gross margin.

Operating profit declined 32% compared to Q4 2017. The decrease is mainly attributable to the decline in revenues and the loss of profit from divestitures and discontinued activities.

We ended with a non-GAAP EPS of $0.53, which declined $0.41 (sic) [$0.40] (18:50) from Q4 2017 due to the decrease in operating income, partially offset by a lower tax rate. We will talk a bit more about the trends in revenue and cash flow later in the presentation.


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So turning to slide 16. As we guided in November, exchange rate movements continued to be a headwind on our revenues in the fourth quarter. We see that the exchange rate movement during the fourth quarter of 2018 had a negative impact of $100 million, while the impact on operating profits was much more modest. The main currencies relevant to our operations that decreased in value against the U.S. dollar were the euro, Argentinian peso, Turkish lira, and Russian ruble.

Turning to slide 17, we'll take a look at some of the revenue trends that we've been seeing through the different segments in the last quarters. Our North American generic business had its strongest quarter of the year, supported by the launch of generic Sensipar and the ongoing exclusive launch of generic Cialis.

COPAXONE saw its largest sequential quarterly drop, as the pace of generic erosion picked up, as well as a reserve taken for the 2019 pricing impacts on trade inventories.

ProAir revenues in 2018 Q4 decreased by 21% compared to 2017, mainly due to the reserve taken in the fourth quarter for utilization shifts in usage and potential return risks following generic competition to the short acting [ph] beta antagonist (20:23) class of drugs, including an approved generic version of Ventolin HFA. And we have launched our own ProAir authorized generic to select customers in January of 2019.

QVAR in the U.S. dropped down to $9 million in the fourth quarter, due to net pricing adjustments.

Revenues in Europe and in our international markets were relatively flat compared to the third quarter of 2018. And I'll address both of these markets in a few minutes when I review our assumption for 2019.

Turning to slide 18. Free cash flow for the quarter was $522 million, a decrease of 181 -- or $182 million versus Q3 2018, primarily due to lower net income, a higher level of legal settlements, and AJOVY launch milestone payments.

For the full year 2018, free cash flow was $3.7 billion, which benefited from $1 billion in one-time items in Q1 attributable to the working capital adjustment with Allergan and the legal settlement with Rimsa, which we've mentioned in previous quarters.

So if we turn to slide 19, we will see the full year 2018 performance, as well as the guidance development for the year. Despite expected headwinds, we were able to exceed our initial guidance. Our business benefited especially from lower than expected erosion of COPAXONE, as well as our continuant efforts to reduce expenses and tax rate favorability.

So turning to slide 19 (sic) [slide 20] (21:57). We'll now present some of the main assumptions for our 2019 outlook, which can also be found in this morning's press release.

The most notable assumption is our global COPAXONE revenues, which we expect to decline by approximately $900 million versus the full year of 2018, mainly in the U.S. But we are also seeing in Europe competition due to the introduction of competing products, putting pressure on prices.

A few slides ago I spoke about ProAir and the drop we saw in the fourth quarter. We expect 2019 sales to be significantly below 2018, due to the introduction of generic Albuterol products, somewhat offset by our own launch of an authorized generic version of ProAir.


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We expect AJOVY to grow nicely in 2019 to approximately $150 million in sales, based on the momentum we've seen since our initial launch last September. We also see AUSTEDO growing to approximately $250 million (sic) [$350 million] (22:54) in sales in 2019.

Turning to our Generics businesses. We see a slight decline in North America, due to erosion in volume declines, offset by our new launches.

In Europe, we expect sales will be impacted by our continual efforts to optimize our portfolio, the full-year effect of the OTC JV dissolution, and continued currency headwinds.

,In our International Generics, we will see pressure on 2019 sales from the adverse impact in Japan, due to the National Health Insurance price revision, as well as from the continued erosion of long listed products. These are products that have lost market exclusivity through the expiration of patent protection and data exclusivity periods. International markets will also be – continue to be impacted by currency headwinds.

On slide 21 we'll continue with our assumptions for 2019, including the impact of foreign exchange, which we expect to negatively impact sales, mainly in the EU and international markets, by $300 million and operating profit by $100 million versus our 2018 full year results. And on this slide, I'd also like to highlight other income, which we expect to -- will significantly decline from the 2018 year total of approximately $200 million.

So now turning to our financial outlook for 2019. Based on the assumptions I just reviewed, we expect total 2019 revenues to be between $17 billion and $17.4 billion.

With the completion of our cost reduction program, we expect non-GAAP operating income to be between $3.8 billion and $4.2 billion, while EBITDA is expected to be between $4.4 billion and $4.8 billion.

Using a share count of approximately 1.1 billion shares, we expect earnings per share to be in the range of $2.20 to $2.50.

Lastly, 2019 free cash flow is expected to be in the range of $1.6 billion to $2 billion.

This now concludes my presentation. We will now open up the call for questions and answers. Operator, if you'd please ask the first question.


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# QUESTION AND ANSWER SECTION

**Operator:** Thank you. Our first question comes from the line of Jason Gerberry. Your line is open.

Jason M. Gerberry
*Analyst, Bank of America Merrill Lynch*

Q

Hey. Good morning, and thanks for taking my question. I guess just first question on 2020. Can you talk a little bit about how you drive a return to growth? There's still a pretty fair amount of COPAXONE in the 2019 number. So if you can just talk a little bit about how you see a broader return to growth.

And just secondly, just on QVAR. Consensus for 2019 is about $227 million, 4Q sales are annualizing at about $35 million. So just can you provide a little bit of color on how you're thinking about QVAR in 2019? Thanks.

Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

A

Yes. Thanks for those two questions. I'll address the 2020. And then Brendan will give you some color to what's been happening with QVAR.

So you would say – if you oversimplify the situation, then you can say, as you mentioned, that the drag on revenue or pressure on revenue from continued reduction in COPAXONE sales. And let's just assume that they're dropping at around 45%. That means that the absolute drag per year goes down. So whereas we had a big drop this year, we will have a smaller drop in terms of the absolute drop in the current year. And again next year it will be smaller again.

Now that drop is being offset by the growth of new products, growth of AUSTEDO, the growth of AJOVY, and the growth in – all over business in terms of new generic launches.

So if you look at that total balance, then it's pretty clear that this year there's more being lost on COPAXONE than is being gained on AUSTEDO, AJOVY, and so on. Whereas in 2020 we'll get to a balance where we believe that at the end of the year, we will see that we are significantly growing more than we are losing. And that will lead to a marginal growth in revenue and operating profit in 2020.

And then once you get into 2021 of course, the loss on COPAXONE is getting close to zero, and that means we get the full benefit of the continued growth of AUSTEDO, AJOVY, and other products worldwide. So that was on the 2020.

On the QVAR, Brendan, could you comment on what we've seen with QVAR? And what we expect going forward?

Brendan O'Grady
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*

A

Yeah, sure. And good morning, Jason. So with QVAR obviously, last year we transitioned from the MDI product to RediHaler product. And that transition occurred in the pipe during the first quarter.


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And it took a little bit longer for the MDI to bleed through the system. And so you saw some prior period adjustments, which is why the net sales ticked down throughout the year.

In the fourth quarter, we got significant Medicaid claims that came in, which further impacted the net sales. But we do see QVAR share returning to about 22%, which is a very good share for QVAR. And if we continue to hold that share throughout the year, you'll see QVAR in that range of $227 million or so, as you noted.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*
A

Next question, please.

**Operator:** The next question comes from the line of David Maris. Please go ahead, your line is open.

David Maris
*Analyst, Wells Fargo Securities LLC*
Q

Good morning. Mike, maybe a broad question. When you look at the Street assumptions of, I don't know, $600 million or $800 million more in EBITDA for 2019 versus your current – or your new guidance, where do you see the largest difference?

And then separately, were there any expenses that were maybe bulked up in 2018, other than maybe a little bit of AUSTEDO or AJOVY expenses that aren't being repeated? And what's the scale of the – what are the scale of those expenses? Thanks.

Michael McClellan
*Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.*
A

Yeah. So I'll take a little bit of a stab at where we see differences versus The Street expectations. And we did mention some of these headwinds in our presentation at JPMorgan.

I think our COPAXONE is a little bit below what the expectations are. Definitely ProAir, we saw in January that there was a launch of an authorized generic to one of our competitors. And we have to look at this class as being generically written for almost the majority of the scripts. So that's causing a big change. And we see a significant decline coming there.

I think we also see that we are going to meet the $3 billion cost saving target, but I think some of the expectations we would go even a little bit further than that.

And then again, we don't have a repeat of this other income that was out there in 2018. And that's putting a little bit of a pressure. So I think those are the main things.

And you combine that with the currency impact. We've seen that in the second half of 2018. And we see that continuing into 2019, being a continued pressure. And when we look at some of the external models, I don't think the same effect has come through as strong as we see it. So those are the main things.

In terms of expenses, we did see a rather flat operating expenses Q4 versus Q4. But you have to remember that in Q4 of 2017, we actually had a period where we reversed the year-to-date bonuses, as we did not pay a 2017 bonus in 2018. So the Q4 last year was a little bit artificially deflated.


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We're still on a good path. But the majority of the actions have been taken out. And we will start to see the spend base in the second half of 2019 start to stabilize with the first – after some decline in the first half. So those are the things that I see. Any other points you want to ask, we can take from there.

David Maris
*Analyst, Wells Fargo Securities LLC*

Q

No, I think, I guess, just as a follow-up on the point of guidance. I've gotten a number of e-mails already that say, okay, well, this just seems sandbagged. And so the stock is down 12% premarket. Just kind of your thoughts on guidance, conservatism. And how conservative do you think this is on the low end? What could go wrong that would get you to that low end?

Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

A

So in terms of the overall guidance. Guidance, in my mind, needs to be realistic and conservative. It's not a sort of an average game where if you get it right every single time, then it's fine. So you can't come out with a guidance that you will meet 50/50.

So you need to have some credibility and some assurance that you can meet your guidance. And I think that's very important when we discuss it.

It's also important that you're in the range of what can realistically happen. And that you have a downward part of your guidance that covers if most things goes wrong.

And you could say there's a lot of moving parts here. We just talked about some of them. You never know how fast a product goes generic. We are assuming that COPAXONE stays on the current trend. It could go faster, it could go slower. You never know how fast you ramp up a product when you have two competitors. AJOVY could go better, AJOVY could go worse. So you have a lot of moving parts.

And then when you give the guidance, you take a educated estimate of all these moving parts. And you explain the assumptions you have. And then of course if someone's assumptions turn out to be worse or better, that affects the actual result. But that's why we explain the assumptions in our guidance.

Next question, please.

**Operator:** Thank you. The next question comes from the line of Louise Chen. Please go ahead.

Louise Chen
*Analyst, Cantor Fitzgerald Securities*

Q

Hi, thanks for taking my questions here. So I had a few. My first question was that you noted 2019 as your trough year. So how should we think about the upward inflection in 2019? Can you give us a sense of the magnitude, even if it's just qualitative?

And then the second thing is, what do you include in your guidance for 2019 in launches in the U.S. and outside the U.S. for generics?

And then, just last here in terms of longer vision for Teva, is it brand? Is it generics? What are you focusing on going forward after this trough period? Thank you.


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**Kåre Schultz**
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

A

So I think, Mike, if you take the first question, and Brendan take the second, then I'll take the last one.

**Michael McClellan**
*Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.*

A

Yeah. So we do see 2019 as the trough at this point. We will see a return to revenue growth in 2020. And I would expect as well an operating profit growth.

But we're probably talking single digits into 2020, and then starting to accelerate beyond there. We still have potential drag in 2020, depending on how the BENDEKA situation in the U.S. turns out. So that's a little bit of a wild card in that. And then of course currencies could be positive or negative versus the 2019, depending on how the markets develop.

**Brendan O'Grady**
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*

A

And so in regard to new generic launches for 2019, I think we see 2019 shaping up very well potentially. Of course any new generic launches are a mix of legal, technical, and regulatory success. So you never really know where that's going to play out.

But we do have some significant launches planned for 2019. So I think that, overall, we should see a fairly good year as far as new generic launches go.

**Kåre Schultz**
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

A

And longer term, after 2019, our vision is to be and continue to be leaders in generics worldwide and to build a strong pipeline and have success in biopharmaceuticals, meaning in both biosimilars and innovative biologics.

And you could say if you want to look at what's then coming, then of course there's the rollout of AJOVY worldwide with the European launches coming up this year and the rest of the world in the coming years.

There's an exciting development project that we have together with Regeneron on pain therapy. And if fasinumab turns out to come out with good safety data and gets approved, then that's an exciting possibility to put people on a non-addictive pain therapy, which will be really, really good. And this is a product we will be, together with Regeneron, then launching both in the U.S. and worldwide.

So there's a lot of exciting things happening. We have a broad pipeline also of biosimilars that we'll be launching in the coming years. So it will be in those areas of continued leadership in generics, both simple and complex generics, and then biopharmaceuticals.

**Michael McClellan**
*Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.*

A

Yeah, and to add to the 2019-2020 point, we would see the inflection actually starting in the back half of 2019 through the quarterly progression.


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Louise Chen
*Analyst, Cantor Fitzgerald Securities*

Q

Thank you.

**Operator**: Thank you.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*

A

Next question.

**Operator**: The next question comes from the line of Gregg Gilbert. Your line is open.

Gregg Gilbert
*Managing Director, SunTrust Robinson Humphrey*

Q

Thanks. Two points of clarification on 2019 guidance on a couple potentially material items. One is, how are you treating the generic risk to TREANDA? And whether and when that happens?

And on the positive side, are you confident in launching – or you're assuming you're launching generic Forteo later in the year.

And then, Kåre, I certainly understand why you don't want the company to spend cash flow and operational time on large acquisitions. What about licensing deals or smaller bolt-ons that will help further your franchises, particularly on the branded side? Do you have flexibility to do that? And are you focused on that? Thanks.

Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

A

Okay. So I suggest that, Mike, if you cover trend; you, Brendan, cover Forteo; and then I'll answer the last question.

Michael McClellan
*Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.*

A

Yeah, so our guidance doesn't include a material impact from TREANDA generics, because it's not likely they'll launch before the very late part of 2019. So there's just a minor impact.

If we do see that the orphan drug exclusivity for BENDEKA keeps the TREANDA generics off the market, there could be a slight upside to what we put forward in 2019. But we don't expect it to be material.

That is actually being handled by our partner, Eagle, as it is their marketing authorization for BENDEKA. And we're not directly involved in the legal discussions there.

Brendan O'Grady
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*

A

In regards to Forteo, it is in the second half of the year of our plan. It continues to proceed as anticipated. We have it appropriately risk adjusted in the overall numbers. But it continues to move along.


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Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*
A

In terms of acquisitions, you're absolutely right. We have no plans of doing any significant acquisitions of any kind. We spent the money basically on reducing our debt.

However, we do of course build a pipeline on an ongoing basis. And of course we are doing business development work in early in-licensing, ensuring that we can get early ideas in that can support our biopharmaceutical pipeline going forward. And of course we are also open to local deals on complex generics, other opportunities that might arise that make sense.

So it's not that we're not active in the business development area. It's just not big corporate deals. It's specific product in-licensing we're talking about.

Gregg Gilbert
*Managing Director, SunTrust Robinson Humphrey*
Q

Thank you.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*
A

Next question.

**Operator**: The next question comes from the line of Chris Schott. Please go ahead, your line is open.

Christopher Schott
*Analyst, JPMorgan Securities LLC*
Q

Great, thanks very much. I just had a couple questions on AJOVY, if I could. I guess the first was, can you just update us at this point on your expectations for gross to net for the drug? And how we should be thinking about the amount of free product that's being provided in the market? I'm just trying to get a better sense of how to ramp the 4Q sales we just saw, relative to the 2019 outlook for that drug.

And then the second question on that same topic. You've obviously seen a very strong uptick so far for the product. But could you just talk about the impact that you see from being – I think you're non-preferred on two of the national formularies. How does that factor into how you're thinking about the competitive landscape for the product at this point? Thank you.

Brendan O'Grady
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*
A

So just a little bit on the gross to net. So as AJOVY continued to evolve throughout the year, and as we get to 2019, one of the things that I think is important to keep in mind is that payer access is going to continue to be fluid. A lot of the discussions are still ongoing.

There's payers that made decisions early in the fourth quarter of 2018. They're going to look at it again in early 2019. I think you'll see some decisions that will change mid-2019. So I don't think the payer landscape really solidifies until probably 2020.


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And of course when you have three products like this that all have very similar efficacy, all launched at the same time, it makes for a rather aggressive payer environment.

So it will continue to be fluid. I think that we have discussions ongoing with many of the payers currently. I think that some of the announcements that have come out, there's still discussions that are ongoing. We are not really excluded anywhere.

So this is all a balance. And you need to balance the access with the appropriate amount of discount and gross-to-net. So I would say that as you look at AJOVY today, we have about 60% coverage in the commercial sector, which I think is fairly good. We continue to add plans throughout the first quarter. We've gotten some wins just recently. And overall, I think that we'll have the appropriate access that we need to hit the number that we're looking to hit, which I think Mike communicated earlier around $150 million.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*

A

Next question.

**Operator**: Next question comes from the line of Randall Stanicky. Your line is open.

Randall Stanicky
*Analyst, RBC Capital Markets LLC*

Q

Great. Thanks. Kåre, are you guys still committed to net leverage below 4 times by the end of 2020? And the reason I ask is because, wouldn't that imply a notable step-up towards $5 billion in EBITDA, if that's the case?

And then secondly, can you just comment on the U.S. Generic gross margin? How much of a step-up or a ramp are we going to see from that? The pruning of $400 million in unprofitable revenue there, I would think should add several hundred basis points to the U.S. gross margin. Can you just confirm if that's the case? And maybe give some directional color going forward? Thanks.

Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

A

So your first question on the 4 times net debt to EBITDA at end of 2020, you're absolutely right that it takes a bit of strong performance in 2020 to get to that at the end of 2020. So I won't be able to tell you firmly that we will for sure hit it exactly at the end of the fourth quarter of 2020. It could be that it's slightly later.

What's most important is of course our long term financial target, which is 3 times. So going below 3 times net debt to EBITDA. And we'll be progressing towards that over the next three to five years. There will be no change in our strategy.

So the exact timing remains to be seen. But the key important driver here is that we are driving towards a constant debt reduction over the coming years.

When it comes to the gross margin, then you could say, when you look at the total picture, which is I guess what you can see in the numbers. Then we had a drag on the gross margin from COPAXONE sales being reduced. The fact that we are reducing the price and the volume of this high margin product means it has a negative effect on our gross margin.


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We've seen a positive effect on our generics, which goes the other way. And we will continue to see a marginal cost effect on our U.S. Generics margin in the coming years.

Michael McClellan
*Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.*
A

Yeah. And if I could add to the debt question. First of all, we expect to pay down the $1.7 billion maturities in July through operating cash flow and cash on hand. We're not expecting to refinance.

And second, we are actively starting discussions with our core banking group to look at reshaping our revolving credit facility to get out in front of getting it to the 12-month window of being current. So we're working on that. And we hope to conclude that in early 2019.

Randall Stanicky
*Analyst, RBC Capital Markets LLC*
Q

Great. Thanks, guys.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*
A

Next question.

**Operator**: Thank you. The next question comes from the line of Vamil Divan. Your line is open.

Vamil K. Divan
*Analyst, Credit Suisse Securities (USA) LLC*
Q

Great. Thanks so much for taking the question. Just maybe following up on the AJOVY commentary and questions. Just you mentioned Europe also as a target market here. And I know we saw some pushback from NICE on Aimovig. So just trying to think about what your expectations there are in terms of timing of launch and sort of the pace that we should expect there. And also maybe net pricing as compared to what we're going to see in the U.S. Thanks.

Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*
A

Thank you for that question. We are of course expecting to have the final you – EU approval very soon. We have a positive opinion. So that means within two months we will have the actual EU approval.

And the way you launch in Europe is really market by market. And that's because, not because you don't have the approval, but because you need reimbursement. And reimbursement is of course something you settle with the governments, the healthcare systems in each of the countries.

So what you will expect is in the markets where it's relatively easy to launch at a good and reasonable and fair price compared to the value of the product, you will see early launches. So this year, for instance, countries like some of the Scandinavian markets, countries like Germany, you will see us launching the product. In other countries, it might take negotiations for one to two years before you end up seeing the launch.


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If we look at our competitors, then you could say that we have a situation here where the European pricing looks to be very similar to U.S. pricing, so we might actually end up with a situation where the net price per patient is higher in Europe than in the U.S., which would be a first I guess. But that's how it's looking right now.

And the unmet need in Europe is huge. But however you see it, it's a slower ramp up due to the fact that you have these prolonged negotiations, especially in the southern European countries. But also in UK, where you have local organizations even that you get into negotiations with.

So we expect a solid and positive uptick but with a slower ramp up than you see in the U.S., but with a good and healthy operating margin on the business.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*
A

Thank you. Next question.

**Operator**: Thank you. The next question comes from the line of David Amsellem. Your line is open.

David Amsellem
*Analyst, Piper Jaffray & Co.*
Q

Thanks. Just a couple. So first, can you talk about – just product specific questions. One is on EpiPen and on the generic. And how you're thinking about the ramp of that product and how the market dynamics for that product will play out?

And also wanted to circle back to Forteo. I know it's in the guidance and risk adjusted. But I did want to get your thoughts on the potential for other entrants and how crowded that market will be. This is more of a 2020 question and beyond. But wanted to get your thoughts on the extent to which that's going to be a sustainable stream of cash flows. Thanks.

Brendan O'Grady
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*
A

Okay. So, David, thank you for the question. So let me – I'll address EpiPen first and then I'll come back to Forteo.

As far as EpiPen goes, of course the market is still in an overall shortage of epinephrine. And we're continuing to manufacture and build more supply. I think you'll see us come into a more normal supply by the end of the first quarter, early second quarter.

And of course then we launch – or we'll have EpiPen Jr late second quarter in the June timeframe. So we continue to build supply. It's getting better. And we have it out there and it's available. So it's available for customers if they need to order it. And we are making nice progress on EpiPen.

As it – and your question around Forteo, we'll have – we'll wait and see. Forteo is not an easy product to make. And we'll see where the competitors come into the market in 2020. But overall, we feel pretty good about Forteo. And we feel pretty good about the runway that we have with it.

David Amsellem
*Analyst, Piper Jaffray & Co.*
Q


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Okay. Then if I may sneak in just another one. In terms of other key launches that you're willing to call out, are there any that we should think about that should be on our radar this year or early next year, sort of limited competition or exclusivity opportunities? Thanks.

Brendan O'Grady
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*
A

Yeah. I mean I think you can think of a couple other ones. I think that Restasis is hopefully a launch for us this year. We'll see where we go with the FDA. We're waiting with FDA action on that product. So that could be a nice product. As well as the other one would be NuvaRing that we're looking at as well this year.

David Amsellem
*Analyst, Piper Jaffray & Co.*
Q

Thanks.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*
A

All right. Next question, please.

**Operator:** Thank you. The next question comes from the line of Ken Cacciatore. Your line is open.

Ken Cacciatore
*Analyst, Cowen & Co. LLC*
Q

Great. Thank you. Just wanted to ask back again on AJOVY and AUSTEDO, where you seem to be doing really well and performing very strongly.

Just specifically on AJOVY, it's our understanding in talking to some consultants that Aimovig may be suffering from a bit of higher constipation than they originally expected. So just wanted to understand in the marketplace right now how much you're benefiting from that? How big of an issue you think it is? Or what are you hearing from your salesforce as they continue to market AJOVY?

And then on AUSTEDO, maybe if you could break down the percentage, HD [Huntington's disease] versus TD [tardive dyskinesia] at this point? And any nuance you can give us on potential dosing advantage? What's going on in the TD marketplace? Again you seem to be showing nice acceleration for that product as well. Thank you.

Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*
A

Thanks for those questions, Ken. I'll give just an overall comment. And then Brendan can give some more details.

It's of course a well-known fact from the labeling and from the clinical trials that Aimovig has constipation as a safety issue. And that's been documented.

When it then comes to anecdotal evidence, it's also quite clear that it is, you could say, an unpleasant side effect on the side effects you have. And in a three-player game, where you have one product that has it and you have two products that do not have it, because they have a slight different mechanism of action, then long term I believe it will be a benefit for us that we don't have this negative side effect.


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It's difficult for us to comment on any specifics there you would -- because we don't have insight into the ongoing safety follow-up and database on that. But for sure there is a product differentiation here, which we think will work to our benefit both in the U.S. and in the European market.

And then I'd also just like to say that on tardive dyskinesia, this is a brand new marketplace and there's never been any drugs before to treat tardive dyskinesia. So it's a huge medical benefit that we're bringing to a lot of people. And I think it will be growing for a long time.

But maybe, Brendan, you can give some more details.

Brendan O'Grady
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*

A

Yeah. So just first a quick comment on AJOVY. So I think that everything that Kåre said regarding AJOVY is obviously accurate.

But the other part of it is that with three of these products launching in relative close proximity and with Aimovig out first, I think when the other two were approved with AJOVY, I think that practitioners and prescribers are going to look at some of the different products and going to use some of the different products to see how they actually result in the real world in patients and see if there are differences.

We designed AJOVY – or the launch of AJOVY to make it really easy for physicians to use and to access. We put samples in the office. Of course the prefilled syringe is a very simple way to inject the product.

So ultimately, we were very happy with the uptick there that we're seeing on AJOVY. And I think that our significant presence in headache centers and with neurologists bodes well for our early success.

So we're happy with where we are. We're going to continue the launch trajectory around AJOVY. And we're very happy with what we're hearing back from physicians and patients regarding the overall effectiveness of the drug.

As we talk about AUSTEDO, I'll just add that we launched AUSTEDO early, first for Huntington's disease. And then came in the market about six months later for tardive dyskinesia. And as Kåre pointed out, that's a very underserved market, and it's a very large market.

So we're happy with the potential that we see for tardive dyskinesia. We have significant salesforce presence around that. We'll continue to drive that indication in that market.

Ken Cacciatore
*Analyst, Cowen & Co. LLC*

Q

Thank you.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*

A

Next question, please.

**Operator**: Thank you. The next question comes from the line of David Risinger. Your line is open.


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David R. Risinger
*Analyst, Morgan Stanley & Co. LLC*

Q

Yes, thanks very much. I have a couple questions. First, could you please comment on the international business outlook? It appears that the international business is performing worse than expected. And I know that you have emphasized the U.S. stabilization. But I didn't hear you previously talk about international weakening.

And then second, with respect to manufacturing, I think, Kåre, you said that when you were – when you had recently joined Teva, you said that if you started the company from scratch, you'd have 12 facilities globally. I think the company's targeting to be at about 65. Could you help us understand why that won't go to 45? Thank you.

Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

A

Thanks for those two questions. If we take the international business first. That is correct that we are having some headwind right now, which is what we have been reporting and what we've also included in our guidance.

And I would say – I would call out two key things. One is the pricing reforms in Japan. The pricing reforms in Japan had led to a bigger drop in the price on what's called long listed products. So these are kind of like branded generics, you could say. And there's a tradition of a high use of those in Japan. And the authorities are pushing down pricing on these products more than they've been doing until recently. So that's a negative.

Then there's the whole currency element, where you could say there's a lot of markets in international markets which have had significant weakening of their currencies, currencies like, for instance, Turkey and many Latin American countries have seen weakening of the currencies.

So you could say it's really not the underlying volume. It's really not the underlying demand in the market that's causing us problems. It's these specifics on pricing and currency that is the main driver.

On the manufacturing side, you quoted me absolutely correctly. And of course one thing is, how you do a greenfield thing? Most countries do not have a manufacturing setup that is the same as they would do if they could do it from scratch.

And that's definitely not the case for us. And we did start – or we didn't start. But when I joined the company, we had around 80 manufacturing facilities. And as I mentioned, today we have closed seven. And we are about to close a dozen more. So we will probably get down to around 60 at the end of the restructuring.

But that of course doesn't mean that we won't do any more going forward. But it's very complex when you close down existing facilities, because you have all the regulatory approvals, have all the validations. Sometimes you have specific equipment. So it takes time.

But we will of course continue to consolidate and improve efficiencies in our manufacturing for the next many, many years. But you will not see the same dramatic reduction as you see in the restructuring period. You will see a more modest reduction in the number of manufacturing sites. And you will see us driving to improve the gross margin of our Generics business on a constant basis.

Michael McClellan
*Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.*

A


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Yeah. And let me add one quick thing to the international markets. There is about a $50 million impact of divestments. We still had women's health sales in the first half of 2018. And we have divested recently the Tevadaptor business, which was announced last week. That'll be another about $30 million drag. So overall, about $50 million is related to divestments of business.

David R. Risinger
*Analyst, Morgan Stanley & Co. LLC*

Q

Thank you.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*

A

Next question, please.

**Operator**: Thank you. The next question comes from the line of Ronny Gal. Your line is open.

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

Q

Good morning, everybody, and thank you for taking my questions. I have three, if I can sneak them in.

First, we just finished analyzing the 2019 formulary coverage in multiple sclerosis. And it seems there's been quite a big shift starting 1Q 2019 about access. Just so we are kind of ready for this idea of volume versus share loss, it looks like you lost coverage in TRICARE, United, and ESI. Is this what you were saying? Is this actually the case here? What we're seeing [ph] externally (57:59) is not always right. And if so, should we be just ready for a significant more volume loss in 2019?

Second, we've heard that post the ESI-Cigna close, there's been a series of pretty sharp demand for concession from all biopharma on the branded side. Is this true? How does this impact your branded product trajectories? And does that also extend to CVS close of Aetna? Essentially, are we seeing the consolidation on the insurance side coming in for further demand for especially older products in competitive markets?

And third, more on the financial side. You're kind of guiding to like $1.8 billion in free cash flow in 2019. This is I guess the bucket from which you pay your debt down. And I'm kind of wondering if that number, just given how much it's lower than 2018, includes any assumptions about paydown off some sort of penalties or fines from some of the existing investigation, or this is kind of like a pure business decline from which we have to start our 2020 projections?

Brendan O'Grady
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*

A

So, Ronny, I'll answer one and two and then I'll let Mike take number three.

As far as overall COPAXONE formulary access, those are things that we built into the plan this year. And I think you can see in our numbers for COPAXONE that we've worked in, we anticipated TRICARE and both UnitedHealthcare.

And I think Express Scripts, which will bridge us to the next question. Express Scripts is always a little bit more of a tricky answer as it goes there. So I wouldn't necessarily assume, depending upon what you see in any particular formulary based on different agreements we have with numerous payers, that just because you read something in


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the formulary is actually how it is going to play out with the various covered lives in any one particular PBM or payer.

As it results to the – as a response to your question with ESI and the meeting that they had, I wasn't there. I think that meeting occurred last week or the week before last.

Aaron Gal
*Senior Analyst, Sanford C. Bernstein & Co. LLC*
Q

Yeah.

Brendan O'Grady
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*
A

Where they brought manufacturers down and kind of rolled out to them the new landscape with the ESI and Cigna merger.

Aaron Gal
*Senior Analyst, Sanford C. Bernstein & Co. LLC*
Q

Right.

Brendan O'Grady
*Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.*
A

Or acquisition, as to what their expectations are. But I do – I've obviously heard we're studying what they've communicated and what their asks are.

I think that it's pretty aggressive. And I think that it's potentially an overreach. There may be some CMS Medicare best price implications to consider. And I think that there will be probably significant manufacturer pushback from what I know of it. But I need to study it a little bit more and get with my team. It's fairly new. And we're looking at the overall impact.

So with that I'll hand it over to Mike, and he can answer the cash flow.

Michael McClellan
*Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.*
A

Yeah. So if we look at the difference between the $3.7 billion that we actually realized in 2018 and the – and say the $1.8 billion midpoint of the guidance, about $1 billion came off from special items that I mentioned earlier, the outlook and working capital and the Rimsa compensation.

Net income is down roughly $600 million to $700 million, so that drags. We will see less restructuring cash out. But we will have bonus payments in 2019 for the 2018 year, which we did not have in 2018 for the 2017 year.

But the thing that is probably abnormal, if you're looking for forward cash generation is, we do have a little bit of an overhang of all of the increase of rebates that have been happening. And in the second half of 2018, we'll have a little bit of a drag on the net receivables in 2019. So we'll have a $300 million to $400 million cash drag that should dissipate over the first couple quarters of 2019.

So that's where we get to the $1.8 billion, which I think that cash drag on the rebate payments is probably the difference between what you would expect in the external models.


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

Q

Great, thank you.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*

A

Next question.

**Operator**: Thank you. The next question comes from the line of Liav Abraham. Your line is open.

Liav Abraham
*Analyst, Citigroup Global Markets, Inc.*

Q

Good morning. Kåre, could you update us on your thoughts on opportunities to rationalize the cost base beyond 2019? You talked a little bit earlier about some opportunities on the plant side. Anything else that you can comment on? And can we expect that $3 billion number to potentially grow?

And then secondly on AJOVY, apologies if I missed this. But can you update us on what percentage of scripts are being written for the once-quarterly formulation? Thank you.

Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

A

Yeah. So first in terms of the spend-base reduction. Then once we've completed the current restructure, we will have reduced it by $3 billion.

And of course there's still opportunities. The majority of those will probably be on the gross margin. And the reason why I'm saying so is that when I look at our R&D spend, our commercial spend, so sales promotion and so on, then we are actually very competitive when we look at the situation at the end of 2019.

So the majority comes from the cost of goods sold from the gross margin. We do have a very high level of cost of goods sold due to the fact that we have very, very high generic volumes. And as I said before, this is something we'll be working on long term.

There's no really quick fix to this, because it's very technically complicated. We do serve more than 200 million patients every day. We do make more than 30,000 different products on an ongoing basis. So it's a big puzzle. But there's certainly possibilities to improve it.

Based on my previous experience, and I won't say that we are having a firm number yet. We will of course tell you about this a year from now. I would say that you can expect that you can improve the gross margin some 50 to 100 basis points per year if you have a really good optimization program in place.

When it comes to AJOVY and the quarterly dosing, we're seeing that roughly in any given week, roughly 10%, 11% of the scripts are for quarterly dosing. That basically means that 30% of the patients, if you look at it from that point of view, are on the quarterly dosing.

And the reason for the difference is of course that if you get a script for the monthly dosing, that counts as one script. If you get a script for the quarterly dosing, it counts as one script but covers three months. So therefore, we


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have this thing we call normalized script numbers, normalized patient numbers. And in those numbers, you could say roughly 30% of the patients are on the quarterly dosing.

Liav Abraham
*Analyst, Citigroup Global Markets, Inc.*

Q

Thank you.

Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*

A

And last question.

**Operator:** Thank you. The last question comes from the line of Esther Rajavelu. Your line is open.

Esther Rajavelu
*Analyst, Oppenheimer & Co. Inc.*

Q

Thank you for squeezing me in. I had one quick one on AUSTEDO. Can you help us understand the sequential change in AUSTEDO patient numbers versus reported revenues for the quarter?

And then also, you mentioned growth in O-U.S. markets for AUSTEDO. So if you can provide any specifics on what your plans are there, that would be helpful as well.

Kåre Schultz
*President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.*

A

Yeah. So if you want to reconcile the actual growth in patient numbers with the actual revenues, then of course that's a little bit of uncertainty on the patient numbers.

And when you look at the actual revenue, there's always the swings, you would say, in the pipeline in the sense that we ship products to wholesalers, to specialty pharmacies. They ship it to patients. And there can be some minor fluctuations there.

If you sort of average it out and look at a longer time series, then you see there's a very strong correlation between the growth in patient numbers, the growth in scripts, and the growth in revenue.

And going forward, we do expect AUSTEDO to be growing strongly. You saw in our assumptions for 2019 that we're assuming sales around $350 million, up from the roughly $200 million we did last year. So we expect AUSTEDO to keep on growing.

And the reason why we are also optimistic about the long term growth is that if you compare our actual patient numbers to the fact that more than 500,000 Americans suffer from tardive dyskinesia, then that gives you a hint about the long term potential of the product.

Michael McClellan
*Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.*

A

Yeah. When it comes to the ex-U.S. markets, there's not going to be any material impact in the near term, as we're still looking at the regulatory path to get the product on the market. So it's not something that really will have a big factoring in the AUSTEDO uptake in the coming years.


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### Esther Rajavelu
*Analyst, Oppenheimer & Co. Inc.*

Q

Got it, thank you.

### Kevin C. Mannix
*Senior Vice President-Investor Relations, Teva Pharmaceutical Industries Ltd.*

All right. Thank you, everybody. I appreciate everybody participating in the call today. We'll be around today, tomorrow, and the coming weeks to take any of your questions. And we look forward to seeing you in the future. Thank you.

**Operator:** Thank you, ladies and gentlemen. A recording of this conference is available by dialing 00443333009785 with the access code 1174907. This does conclude the conference for today. Thank you for participating. You may all disconnect.

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