07-Nov-2019

Teva Pharmaceutical Industries Ltd.

(TEVA)

Q3 2019 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by, and welcome to the Teva Pharmaceuticals Third Quarter 2019 Financial Results Conference Call. At his time, all participants are in listen-only mode. There will be a presentation followed by a question and answer session. [Operator Instructions] I must advise you the conference is being recorded today.

I would now like to hand the conference over to your first speaker today, Kevin Mannix. Please go ahead.

Kevin C. Mannix

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

Thank you, Laura, and thank you, everyone, for joining us today to discuss Teva's third quarter 2019 financial results. We hope you've had an opportunity to review our earnings press release. A copy of the release as well as a copy of the slides being presented on this call can be found on our website at www.tevapharm (sic) [www.tevapharm.com] (1:07), 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; and Mike McClellan, Teva's Chief Financial Officer, will review the third quarter results. Question and answer session will follow their presentation. Joining Kåre and Mike on the call today is Brendan O'Grady, Teva's Head of North America Commercial.

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

Kåre Schultz

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

Thank you, Kevin, and welcome, everybody. It's a pleasure to review the third quarter highlights.

Our revenues came in at a bit more than $4 billion, very much in line with the last three quarters, as we've been discussing before. We are seeing now a nice, stable development of our revenues.

Our GAAP diluted loss per share was $0.29 in the third quarter. This was primarily affected by the accrual for the opioid litigation. On a non-GAAP basis, our diluted earnings per share were $0.58. The primary change there was a change to the tax, estimated tax for the full year, and that reduced the EPS by around $0.04.

The non-GAAP EBITDA is around a bit more than $1 billion. It's very stable, again, the last three quarters. So really the take-home measures here is we are seeing the operational stabilization we've been talking about. We

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can see that the run rate on the operating profit is stable. And we also saw a nice cash flow of some $550 million in the third quarter. So all in all, we are very happy about the financial results.

Commercially, I'll touch upon a few topics. I'll touch upon North American generics, the nice growth we see in AUSTEDO, TRUXIMA, which is a new launch we are having in biosimilars. And then of course also on the restructuring program and in positive development of our net debt.

But let's go first to the restructuring and take a status on that. So if we can take a look here at the actual spend base in 2017, it was $16.3 billion. As some of you might recall, when we announced the restructuring nearly two years ago, we promised we would bring this down by $3 billion to an absolute number of $13.3 billion in 2019. We are perfectly on track to doing that.

You can see here that the MAT right now is $13.4 billion. But of course as we swap the fourth quarter last year with the fourth quarter this year, when we complete the year, we can see from all indications that we will hit the $3 billion cost reduction.

This has of course come through thousands of actions and initiatives around the world. And we've seen the number of FTEs go down by more than 11,500. And we also are in the continued process of restructuring our manufacturing network. And right now we have in the period closed down or sold 11 sites. And we have five more sites where we have announced that they are in the process of being closed or divested by the end of 2019.

So we are approaching just above 60 manufacturing sites. And that's, of course, a very complex and ongoing process. But that's the background also for the reduction in the spend level, which we're very, of course, satisfied with.

The long term target remains a reduction of our net debt-to-EBITDA below 3x. There's no change there. And we continue to allocate by far most of our cash flow to the reduction in debt. And I'm happy to show you here that in the same restructuring period, we have so far been able to reduce the debt by US$8.3 billion.

If we look at the global generic sales, then you can also see a stabilization here. Of course, these sales will always swing a little bit quarter by quarter, depending on the actual launches that we're seeing.

But we've seen a very high number of launches this year. I think year to date in the US alone, we have about 40 launches. So we see a very healthy business, basically driven by the fact that we had more generic projects in the pipeline than anyone else. And that naturally leads to a high level of launch activity, both in the US and in Europe and in the international markets.

So very satisfied with that stabilization. And it goes hand in hand with an overall stabilization of the pricing environment, both in North America and in Europe on generics.

If we look at AUSTEDO, then the successful penetration of the market continues both for Huntington's dyskinesia (sic) [Huntington's disease] (6:35) and for tardive dyskinesia.

And if you look at the revenue, it's a little up and down for the quarter. But that's more due to random elements of shipments and so on. And we continue to see a strong growth. And we expect the product to keep growing.

I've told you before that in tardive dyskinesia we have an estimated patient population potentially of some 500,000 Americans suffering from tardive dyskinesia. And we have one competitor. But between us and that one

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competitor, we are still only at a very low level of patients receiving treatment in the US. So we're quite convinced that this product can keep on growing for the foreseeable future.

If we move to AJOVY, then AJOVY is off to a very good start. We see increased revenues. We have a normalized TRx share right now of around 19%.

We've seen a weakening of the new to brand share. We contribute this to the lack of us having an autoinjector. And as the class is penetrating more and more, we see patients deciding to go for products that have an autoinjector.

We're expecting a positive clarification with FDA on the approval of our autoinjector for the US in the coming months. And we've just received the positive opinion from CHMP in Europe. So we will be launching the autoinjector in Europe also in the coming months.

On COPAXONE, I'm happy to share with you the sales numbers for the third quarter. We saw a very stable development both in North America as well as in Europe. So this is of course very positive. We continue to see a slow erosion in the TRx count in North America. And we are optimistic that we will maintain a significant business in COPAXONE, both in North America and in Europe.

One announcement we've made today is the anticipated launch of TRUXIMA, the first approved rituximab biosimilar in the US. We'll be launching on November 11. And this will be with a full oncology label.

This is very exciting, because as you know, part of our strategy is leadership in biopharmaceuticals, including biologics, such as biosimilars. And so far, we have seen biosimilars penetrate less in United States than they have been penetrating in Europe.

We believe that there are several reasons for that. And one of the reasons is that in order to penetrate, you need, of course, competitive pricing. But you also need dedicated patient support and services. And you also need a good commercial footprint in the area where you're penetrating.

And due to our long experience and strong position in oncology, we believe that we know how to penetrate this market to the benefit of both patients and payers in the oncology space in the United States. So this is going to be very exciting. And I'll be sharing with you in three months how we actually end up performing.

I'm sure that one thing that's on everybody's mind is the opioid litigation situation. We were happy to settle the Track 1. But we were even more happy to see an agreement in principle with a group of attorney generals.

We believe that the agreement in principle is the best way forward for the patients, the people in United States suffering from addiction. We believe our commitment to supplying Suboxone generic for the next 10 years to all the people suffering from addiction who can use this product to get out of their addiction. And it can be a element in that whole process. That that's the best way forward.

We hope that this framework will materialize. And that in materializing together with other defendants, we will be able to help alleviate some of the burden from the misuse of opioids in the United States.

If we look to the future focus and the present focus, then of course we remain focused on maximizing the profits from our existing core businesses. We remain focused on increasing the sales of our new brands, such as

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AUSTEDO and AJOVY. And I should add that we are working on the launches. We are launching AUSTEDO and AJOVY in more countries as we speak.

And also in the coming period, we are executing on our biopharmaceutical R&D strategy. And I'll be sharing more of that with you in February.

And as well in February I will share with you our manufacturing strategy, which will, of course, be focusing on delivering efficiencies and optimization. And all of this we do to secure strong free cash flow and, of course, secure the debt repayment.

And before I turn over to Mike, I would like to add a few extra elements. One is a warm thanks to Mike for the great collaboration I've had with him over the last two years and for everything he has done for Teva.

As you know, Mike is leaving the company for personal reasons. And he committed to stay on until today. And I am very grateful for that.

We have announced today also that we have appointed a new CFO, Eli Kalif, who has a strong background in finance and manufacturing as well as other relevant elements for us. He will be starting on the 27 of December. And until then I will be your interim CFO.

So with that, I'll hand over to Mike.

Michael McClellan

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

Thank you, Kåre, and good morning, everyone. As always, we start with a review on the GAAP performance on slide 15. Teva posted a quarterly GAAP loss of $314 million and a loss per share on a GAAP basis of $0.29 for the third quarter of 2009 (sic) [2019] (13:06). As I'll detail in the next slide, the GAAP results were impacted mainly by an update to our legal provision associated with the ongoing opioid litigation.

So turning to slide 16. In the third quarter of 2019, non-GAAP adjustments amounted to $951 million impact on net income. The adjustments came primarily from three items, a $460 million (sic) [$468 million] (13:30) provision for legal settlements, generally related to the opioid litigation; amortization charges of $255 million, which is a normal quarterly run rate for us; and $204 million impairment to intangible assets.

I'd like to take a minute and give you some insight into how we calculated the legal settlement provision, as it relates to ongoing opioid litigation. As you recall that in Q2, after considering the $85 million settlement we had with Oklahoma and its unique characteristics, we further evaluated the potential settlement scenarios and outcomes for the purpose of determining the size of the provision we would take.

And in accordance with accounting requirements, as no single scenario was considered to be most probable at that time, we recorded the minimum of these estimates, which in Q2 was approximately $500 million.

Since then, we've had two additional data points, which are, A, our Track 1 settlement with the two counties in Ohio, and B, the not yet finalized agreement in principle on a nationwide settlement framework announced on October 21. These data points and other factors were taken into consideration in our ongoing evaluation of potential settlement scenarios and the outcomes, which resulted in increasing the provision by about $450 million to its current total of approximately $1 billion.

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As in accordance with the accounting requirements, when no scenario was considered most probable, we are required to record the minimum of these range of estimates.

In addition, this quarter we took an impairment of $204 million, which brings the year-to-date impairment number to approximately $1.2 billion on intangible assets. These are mostly comprised of intangible assets and product rights, as well as IPR&D assets related to the Actavis Generics acquisition.

Now turning to our non-GAAP performance on slide 17. Quarterly revenues were $4.3 billion, a decrease of $265 million or 6% compared to the third quarter of 2018. The decrease was mainly due to generic competition to COPAXONE, a decline in revenues from TREANDA and BENDEKA, and lower sales in Russia and Japan. This was partially offset by higher revenues from the progress of our launches of AUSTEDO and AJOVY in the US, a recovery in QVAR, and strong trends in our Anda business in the US.

Gross margin was 49.3% compared to 49.9% for the same period in 2018. The change in gross margin was driven by the decline in COPAXONE and bendamustine revenues in the US, which were partially offset by improved profitability of our North American generics business and growing sales of AUSTEDO and AJOVY.

Operating income in the quarter declined by 5% compared to the same period of 2018. The decrease was mainly attributable to the decline of COPAXONE and other specialty brands. These declines were partially offset by cost reductions in Europe as well as increased sales of AUSTEDO in the US.

Non-GAAP earnings per share in the quarter were $0.58, $0.10 lower than the same period of last year. The decrease was mainly due to operating profit and higher tax expense, partially offset by lower financial expenses.

I'd like to take a minute, though, to describe what we're seeing in the development of our expected tax rate for 2019. At the start of the year, we guided for an expected tax rate of approximately 16%. We now expect our annual tax rate for 2019 to be closer to 18%.

The increase, which is mainly driven by US losses which do not have a tax benefit, interest expense disallowance coming from the further development of the US tax reform in our accounts, and other changes to tax positions. The change in the tax rate in Q3, plus the catch-up for the first two quarters of 2019, reduced our Q3 EPS by approximately $0.04 as Kåre mentioned earlier.

Turning to slide 18. We have been highlighting for several quarters now, including in our 2019 guidance provided in February, the impact of the stronger US dollar on our results, since approximately 50% of our revenues come from sales denominated in non-US dollar currencies.

We see that the exchange rate movements during the third quarter of 2019 had a negative impact of $55 million on revenues, while the impact on operating profit was smaller at $22 million. The main currencies relevant to our operations that decreased the most in value against the US dollar were the euro at 4% and the pound at about 5%. We expect that the US dollar will remain strong for the remainder of the year.

Turning to slide 19. Free cash flow for the quarter came in at $551 million, an increase of $383 million versus the second quarter of 2019. The significant increase in free cash flow in the year was mainly attributable to the expected improvements in working capital that I previously guided to.

I'd remind you that the working capital was a drag on cash in the amount of $365 million and $345 million in the first and second quarters respectively. However, working capital was basically neutral in the third quarter of 2019.

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So turning to slide 20. We ended the third quarter with a net debt of $25.7 billion and a net debt-to-EBITDA ratio of 5.62x. We are especially pleased to see a reversal of the upward trend of the ratio from the previous four quarters, as this is the first time since the Actavis acquisition that we have seen a decline in this ratio.

In the course of Q3 2019, we did borrow $500 million under our revolving credit facility. And we subsequently repaid $400 million of such borrowings. During the month of October, we repaid the remaining $100 million. And as of today, we have no outstanding draw on our revolving credit facility.

So turning to the financial outlook for 2019. Today, we are revising our five main financial targets, based on the performance of the first nine months and what we're seeing for the fourth quarter. As you can see on the updated outlook, we basically brought up the bottom end of the ranges of all of our parameters. Where we end up in these ranges will be determined mainly by the penetration of the TRUXIMA launch in the US, COPAXONE trends, foreign exchange effects, and our product mix in our generic business for the rest of the year.

So lastly, on a personal note, as you know, today marks my final earnings call as Teva's CFO. I'd like to say that it's been a real honor and privilege to serve in this position the last two years.

I'm especially proud of the work that my talented and dedicated group of employees in this great company have accomplished. And I believe the company will only grow stronger in the future.

I wish Eli Kalif great success as he takes over this important role. And to the members of the investment community, I've always appreciated your thoughtful questions and helpful feedback. And our investor goal and relations goal has always been and will continue to be to communicate with the investors clearly and concisely as we possibly can. Thank you.

And now we'll open the floor up for questions and answers.

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QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Please be advised you will be limited to two questions. If you have more than two questions, we kindly request you go back to the queue.

Your first question comes from line of Elliot Wilbur. Please ask your question.

Elliot Wilbur
Analyst, Raymond James & Associates, Inc.

Q

Thanks, and good morning. And best wishes to you, Mike. And thanks for all your help over the past couple of years.

Question specifically with respect to gross margin performance in the quarter. A little bit lighter than expected. and I know there's been quite a bit of focus on that this morning, sort of given how important that is to you ultimately reaching your operating margin target.

I guess drilling down through the numbers a little bit, it looks like everything in terms of segments was essentially flat sequentially with the exception of the international business, was down about 200 basis points. So I don't know if that's a function of exchange or just plant utilization. But maybe you could just drill down on those dynamics a little bit more? And sort of talk about what accounted for the relative softness there?

And then as a follow up for, I guess, Kåre and Brendan, just maybe some thoughts on kind of overall CGRP market dynamics in the US? If the positive is we still see 7,000 kind of new to brand Rxs every week. But that's basically been flat for eight months. So just thoughts on maybe sort of overall market growth trends, opposed to just Teva's relative share of the market. Thanks.

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

A

Thank you very much for those questions. I think Mike will take the first ones. And then I'll give it a go at the second one. And then Brendan will add to that. So, Mike, you go first.

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

A

Yeah, so we did have a sequential dip, if you look Q2 to Q3, in the gross margin percentage. But we also had that last year. So it's a little bit of a normal pattern in the year. We do expect that the full year and the Q4 will get back towards the 50%.

If we actually look at what drives that in the Q3, a couple things. You're right, the international markets, we saw a little bit of a lower gross profit percentage there, mainly related to Japan. We've seen some product mix there that's a little bit light in the quarter.

We also have a little bit higher write-offs in the quarter versus what we'd had in Q2. That tends to happen in the summer months, as you have some plant shutdowns, and they re-evaluate the write-offs of products. But we still feel good that we're on track for roughly 50% for the year. And you should see around that level in Q4.

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

A

And on the overall CGRP dynamics in the US, I would just say that from an overall perspective, we are still very optimistic about this segment. We see a very good reception in the marketplace in terms of efficacy. We see a constant good flowing, as you mentioned yourself, of NBRx, which means that the market continues to accumulate.

So we're still very optimistic on this segment. And also internationally, we are only just starting to launch in Europe and in the rest of the world. But we believe this will be a strong worldwide segment. Brendan, do you have any further comments?

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

A

Yeah, I would just comment, Kåre, that I think if you look at this segment, as Kåre mentioned, it's a very effective class of medications. And I think you saw a lot of early pent-up demand.

And I've said since the beginning, 2019 was going to be a bit of a roller coaster. I do think that the market levels out a little bit and continues to grow. And I think that we'll play a significant part in that growth.

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

A

Thank you, Brendan.

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

A

Next question?

Operator: The next question comes from line of Ken Cacciatore. Please go ahead, your line is open.

Ken Cacciatore
Analyst, Cowen and Compnay LLC

Q

Thanks so much. Kåre, you're doing a great job trying to resolve this litigation. But can you just give us a sense of dealing with all attorney generals versus some? Are we making any progress with those that are not part of this early agreement that you have? So is there any progress being made as you try to bring the rest of them under the tent?

And then also in terms of the upcoming debt that you have due in the next couple years, can you just talk about how this litigation may be impacting your ability to refinance or work on that, on those debt obligations? Thank you.

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

A

Thank you very much for that question. I'm sure that it's on everybody's mind, the litigation on opioids.

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And what I'll say on that is that the framework has of course been developed together with the four AGs that have been sort of been a party to this. And it was started based on the Track 1 case that was coming up, as you know, in Cleveland.

And the way it's developing is basically that there's a framework that everybody agrees to. And that will serve, you could say, the American public and will serve the people suffering from addiction very well.

We have made a 10-year commitment to supply a key component in the treatment pattern for people suffering from addiction. Some of the other defendants have made commitments to provide significant financial resources also over a longer period of time.

And I feel this will be a very, very good way to move on. Because at the end of the day, what matters is really if we alleviate some of the burden from the people who have problems with addiction.

Now that being said, of course, I realize that this will only work if everybody comes together. I very much hope that everybody will come together. That was the whole idea behind it. That's what the AGs have been signaling to us.

It's a process that's ongoing. I'm sure it's an interesting and dynamic process. But I have high hopes that we will succeed in the end to the best of the American public, but also to the best of everybody involved.

Now when it comes to the ongoing, you could say, challenge we have, that we need to secure a refinancing in order to serve our debt, then I don't think it's a major issue. I think what matters here is that there's a willingness to look at a longer period here, to look at like a 10-year period in order to resolve the issue.

And that of course means that on a short term basis, given the fact that as we just discussed, we have a high debt and we have a high net debt to EBITDA ratio, then the fact that we were looking at a longer term solution, is a positive for our ability to, on an ongoing basis, refinance our debt. And maybe, Mike, you have a comment?

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

A

Yes. We regularly assess the market conditions as they relate to refinance our debt. And at this point we can't comment on specific refinancing plans. But I think we've mentioned in the past that we would like to get out in front of the 2021 maturity sometime, latest in the first half of next year.

So we'll continue to monitor the market conditions and look at refinancing when it makes sense. We have been encouraged by the recent moves both in the broader market interest rates as well as in our own secondary rate. So there is some things that we will look at and assess the market as the time comes.

Operator: Thank you. We will now take our next question from the line of Esther Rajavelu of Oppenheimer. Please go ahead.

Esther Rajavelu
Analyst, Oppenheimer & Co., Inc.

Q

Good morning. A couple quick ones. On AUSTEDO, can you update us on the Tourette's syndrome readout?

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

Yes. Sure. So we expect to have the final results of Tourette's in the first half of next year. And of course, as soon as we have the final results, we will communicate them to the market.

At this point in time we don't really have any further information. But of course, we very much hope for a positive outcome to the benefit of patients suffering from Tourette's.

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

Got you. And then you mention in the press release on investing in some early stage R&D projects. Can you help us understand what they are? And when we might be able to see some of the news flow on those?

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

Yes. We have a strategy where we are pursuing R&D in biopharmaceuticals. Now that's innovative biopharmaceuticals and it's also biologics, such as biosimilars.

And we will be communicating more in depth on the R&D strategy and the portfolio in February in connection with our full year announcement. Right now, all I can say is that we have approximately 25 biopharmaceutical projects. And it's a very, I think, exciting portfolio that fits with our commercial footprint as well. But I don't have any further comment today.

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

Okay. And then lastly, any update on the price-fixing litigation?

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

There's no real update there. It's, we are in ongoing dialogue with the Department of Justice. We have, of course, shared more than 1 million documents with them. We've not found any evidence that we were in any way part of any structured collusion or price fixing. But we remain, of course, in dialogue with the Department of Justice.

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

Thank you.

Operator: Thank you. The next question comes from the line of Gregg Gilbert from SunTrust. Please ask your question.

Gregg Gilbert
Analyst, SunTrust Robinson Humphrey, Inc.
Q

Thank you. Kåre, I know you plan to update in February on this, but you did replace your Head of Global Ops a few weeks ago. So I was hoping you could provide a little more color on that. And update us on your progress to

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streamline your global operations and reduce cost of goods. It seems like cost of goods is the next frontier in terms of cost reduction at Teva, given the low hanging fruit you probably already picked in the other lines.

And my second question is for Brendan. When do you expect approval for generic versions of FORTEO and NuvaRing? And can you update us on expected launch activity in general in the coming months? Thanks.

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

So thanks for that question. You're absolutely right. Of course, it's a key topic for us to secure that we can, long term, improve our operating margin and our gross margin.

And you could say that the recent change we had in the head of our global manufacturing, in that change we replaced a very experienced and a very, very competent person with another very experienced, very, very competent person. And we also in our choice of new CFO have secured a person with a very long and in-depth experience in global complex manufacturing and margin improvement.

So I'm convinced that the management team will be able to inform you about our manufacturing strategy and the positive effects it will have on our gross margin long term. And we will be doing so with more color, more detail in February.

But you're absolutely right. It's one of our key priorities for the very simple reason, our gross margin is around 50%. And that means basically, every dollar we sell, we spend $0.50, by far the biggest cost element in our P&L on the manufacturing. So that's, of course, a key focus area for us going forward. But more details on it in February.

And then on to you, Brendan?

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

Yeah, so, as Kåre mentioned, we've launched 40 generic projects year to date. We have another five to eight that we'll complete by the end of the year.

NuvaRing, FORTEO, and RESTASIS, none of those are in the 2019 plan. We likely won't launch FORTEO before the second half of 2020. NuvaRing has been moved out to 2020. And RESTASIS could be any day. We just don't really know kind of on that one. So whenever the FDA approves it, we're operationally ready to go.

Gregg Gilbert
Analyst, SunTrust Robinson Humphrey, Inc.
Q

Thanks for the color.

Operator: Thank you. We will now take our next question from David Risinger from Morgan Stanley. Please go ahead. Your line is open.

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

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Thanks very much. Two questions, please. First, with respect to the proposed opioid settlement, could you just explain how Teva accounts for the $23 billion in free Suboxone over 10 years from a financial exposure standpoint in reserves? So how you book that into reserves? Or do not book that into reserves?

And then with respect to AJOVY, could you talk about potential formulary changes in 2020? Any opportunities to improve its position that we should know about? Thank you.

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

A

Thank you very much. I'll take the first one. And then Mike will probably add something to it. And then Brendan will address the AJOVY formulary question.

So if you go back to the half year announcement. And at that point in time, as you know, we have had the first settlement in Oklahoma. And the way the accounting rules are, like, if you have a settlement but you don't know really what the end result will be for the whole issue, you have a partial settlement.

Then what you're supposed to do is you're supposed to assess what the likely outcomes are. And if there's not one outcome which is the most likely, then you will pick the lower end of the range of outcomes that are sort of within the likely scenario.

So since then, of course, we've had two things happening. We've been settling the Track 1 in Cleveland. And then we have the framework, which still has not been finalized, meaning that we don't have it sort of in a final form. And we don't know exactly how it's going to play out.

So we've taken all these things into account, including the commitment to – under the framework, which we hope very much will come to fruition under the framework, to commit to, at WAC pricing, deliver $23 billion of Suboxone.

And that all those elements have been taken into account. And that has then led to a range of possible outcomes. And we have then made an accrual, which matches the lower end of the range.

But, Mike, I'm sure I didn't get it all right. But if you have some further comments, please?

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

A

No, I think you got the substance right. Let me just get some of the mechanics to expand on it.

So our expectation is that we will book a reserve for the future costs of this settlement, whether it be the cash costs or the cost of goods. Some of those elements will be discounted using an appropriate discount rate back to a present value.

Over time, what you will see is, as inventory is produced and released, it will be taken against that reserve, as well as cash settlements as part of a future cash outflow.

And over the years, the reserve will then of course be evaluated on an ongoing basis for changes in cost of goods, changes in interest rates, or any other thing that may change that liability. But our expectation is to eventually, once there's a final settlement with everyone, that you will see a much more clear number.

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As Kåre mentioned, we've got a range of estimates at this point. And as nothing is more probable than any other point on the range at this point, we booked the minimum of what we expect.

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

So as far as AJOVY formulary access for 2020, we don't expect any major negative changes to our formulary position going into 2020. We have currently about 70% what we would call acceptable access or acceptable coverage. And we hope to continue to improve that, especially as we go into 2020.

We have one major Blues plan coming on that we know of in January 1, so that'll help. And although there's not a lot of volume in Medicaid and Medicare Part D, we're looking at those segments as well and improving our coverage there also.

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

Thank you.

Operator: Thank you. The next question comes from line of Ronny Gal from Bernstein. Please ask your question.

Ronny Gal
Analyst, Sanford C. Bernstein & Co. LLC
Q

Good morning, everybody. Congratulations on the nice quarter. And, Michael, I will miss you. We always enjoyed working with you.

If you don't mind, I'm going to kind of give you guys three, but all the same topic, which is roughly pricing. I was wondering with TRUXIMA, if you can let us know what [ph] price you came with (37:49)? Is it the same WAC as the innovator, same as the current ASP?

And now that you're launching this product commercially, I was wondering if you could share with us a bit more about the margin that you'll be making on sales from your partnership with Celltrion?

Then just following up on a couple of the questions that just came in. On the settlements with – on the opioid settlement, can you let us know, or share with us roughly, what would be the drag on cash flows if the agreement with the four AGs will actually end up being the agreement that passes the entire country as is? Just so we can kind of model the probability.

And the question of the pricing for 2019, AUSTEDO and AJOVY, now that we have the contracts for 2019, can you give a feel for the pricing trend? Are we going up moderately? Or is it more of a flat or a step down, given the contract situation?

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

Okay. Thank you, Ronny, for those questions. The TRUXIMA question and the AUSTEDO question I will leave for Brendan. But I'll just handle the opioid first.

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And with regard to the opioid framework, it's really too early to give you a firm answer to this on the cash flow. And that's simply because we haven't really, you could say, got to the fine print on it. And there's a lot of details about how will the ramp-up of on volumes be? And how will it actually be executed? So it's too early for us to give you a number for the actual cash flow.

Assuming that the framework results in a firm agreement, which I very much hope, as I said to the benefit of the American people and people suffering from addiction, we will, of course, update you as soon as that has happened with a more precise number, both on the accrual and on the effect on cash flow.

And then, Brendan, over to you.

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

Sure. So, Ronny, the press release on TRUXIMA has the WAC prices listed in there. So it's $845.55 for the 100mg vile. It's $4,227.75 for the 500mg vile, which represents I believe about a 10% below the reference brand WAC. Of course, we will likely sell it for something less than that.

I won't get into the exact specifics of how we're going to do that and the channels we're going to do that and so forth. But I think you're kind of aware of how this will go.

As far as the margin, this is a profit split between us and Celltrion. Celltrion were the developers. They submitted the DLA to the FDA. And our deal and our profit split acknowledges the partnership that we have with Celltrion. So that's all I'll comment about that.

In regards to AUSTEDO and AJOVY, I think as we have – we convert patients off of coupon cards, we have more patients in paid prescriptions, and we continue to improve our formulary access, you'll see the margins on AJOVY improve. And I don't see any real significant change to the margin on AUSTEDO as we head into 2020.

Ronny Gal
Analyst, Sanford C. Bernstein & Co. LLC
Q

Thank you.

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

And maybe just to add to that on AUSTEDO, if we take price adjustments on AUSTEDO, it will be [ph] at most (41:01).

Ronny Gal
Analyst, Sanford C. Bernstein & Co. LLC
Q

Thank you.

Operator: Thank you. Our next question comes from the line of Ami Fadia from SVB Leerink. Please ask your question.

Eason Lee
Analyst, SVB Leerink LLC
Q

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Good morning. This is Eason Lee on for Ami. Thank you for taking my questions.

Just a couple sort of on the biosimilars. We've seen some different biosimilars, Neulasta, Remicade launches in the US priorly. And they've gotten off to different ramps. And acknowledge that sort of their different patient populations and durations.

So just given these dynamics, how are you sort of thinking about the launch curve of biosimilar RITUXAN versus some of these?

And then just on some of the other biosimilars in your pipeline, Herceptin, when is this expected to hit the market?

And then maybe a broader question longer term, what is your appetite to sort of bringing on additional biosimilars into the pipeline? Thank you.

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

A

So I think I'll address the last one, the broader question, and then I'll leave the two specific ones for Brendan.

So longer term, we actually have a appetite for bringing specific biosimilars to the marketplace. We realize that it's a unique situation product by product. And we firmly believe that in order to be successful with a biosimilar in the US marketplace, you need to have the, I would say, commercial footprint and commercial insight in order to penetrate the market.

In this case, as I said before with TRUXIMA, we believe that due to our long experience in the oncology space in the US with several products in the marketplace and long standing relationships with all the different parts of the commercial value chain, that we have a very good chance of doing so.

And we also believe that in the future, we will be able to do the same with many different biosimilars. So that's a part of our, I would say, biopharmaceutical R&D strategy that we both work on innovative new biologics but also on biosimilars.

But on the specifics, over to you, Brendan.

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

A

Yeah. As you can imagine, there's been a lot of interest in the biosimilar launch of RITUXAN. So there's been a lot of interest TRUXIMA. And of course, Pfizer will follow on after us. So there would be two in the market here in the not too distant future.

I think it still remains to be determined how pricing shakes out and what the uptake is on share. But we're fairly optimistic that we have the right mix to take advantage of it.

If you think about who Teva is as an organization, we have an oncology business that we're very familiar with. And we have a product in that portfolio, GRANIX, that very much acts like a biosimilar. And then we have, of course, the generic business. And the biosimilars are somewhere between a brand and generic.

So we think we have the right commercial structure and the right strategy to fully take advantage of this marketplace, maybe uniquely better than most. So we'll see where it all goes. We look forward to showing you the

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results when we get there to February. But we're optimistic that we will see fairly good uptake in this market and maybe better than what we've seen with some past biosimilars.

In regards to Herceptin, I think you asked when we were planning to launch Herceptin. And it'll be late Q1, I believe, is the date for Herceptin, which is – our product is HERZUMA.

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 Dana Flanders of Guggenheim. Please ask your question.

Dana Flanders
Analyst, Guggenheim Securities LLC
Q

Hi. Thank you very much for the questions. My first is, Kåre, I know you've talked about the US generic business being about $4 billion in annual sales. And I know it can be lumpy. It seems to be trending lower this year. And you pushed out some launches.

So just can you comment on how much wiggle room you see to that $4 billion number? And would you expect launches next year to take that US number back to that annualized $4 billion run rate?

And then just my second quick follow-up. On AJOVY, and I recognize the importance of having an autoinjector, can you just talk about the need or lack thereof of a primary care presence to really help drive NRx back to where you'd like to see it go? Thanks.

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

Thank you for the questions. I'll take the first one. Then I think Brendan and I will share the second one.

So in terms of the $4 billion, it's important just to remember what we've been saying all the time. We are saying North America. So if you look into detailed numbers, it's not the United States alone. It's United States and Canada. And as you know, we have a very strong generic business in Canada as well.

So the North American business has a run rate which is very close to $4 billion. And as you say correctly, it can be a bit up and down, the quarter. I think this year it will be very close to $4 billion in total.

And I have the same rough expectations for next year. We'll give you more insight into that of course when we come out with the guidance in February for 2020. But we do see a strong and sustainable business.

And you're absolutely right. Some of our launches will get delayed. Others will move up. Some will do better than expected when they finally get there, like EpiPen and EpiPen Jr. And others, we'll be disappointed that they get delayed. So that's just the name of the game in generics.

And with regards to AJOVY, I think I'll let you go with that one, Brendan.

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

A

Sure. So we've always looked at the CGRP market and specifically the AJOVY launch as a two-phase launch for us.

So we launched the prefilled syringe into the market. We saw early – a lot of early quick demand. And of course in the last several months we've seen a decline in the new to brand share. And largely, we believe that that is due to patient preference of the autoinjector.

So when we speak to physicians and we talk to them about AJOVY, they're certainly very happy with the clinical profile, the side effect profile, the way patients respond to it. And they really don't see much of a downside in a prefilled syringe. In fact, one of the things they continue to ask us is, are we going to keep the prefilled syringe on the market once we launch the autoinjector? And of course, we are, because they see a big benefit of that.

But when you put the products, all three, in front of a patient, they seem to prefer at a very high rate the autoinjector over the prefilled syringe. So I think that that's largely what we're seeing. And that's the reason for the decrease in the new-to-brand share.

So I think when we launch the autoinjector here in the coming months, we'll see a continued bump and kind of the second curve up in the launch of AJOVY.

But in regards to your comment about the primary care sales force, we actually do have a primary care sales force selling AJOVY. We have two sales forces selling AJOVY. We have our neurology salesforce, which is calling on headache centers and neurologists. And then we have what we call our specialty sales force that's calling on high decile primary care writers as well as non-neurology high decile headache specialists.

So we feel that we've got the right promotional mix from a sales rep standpoint. But certainly we don't have as deep of relationships with primary care as some of our competitors. So I think it's going to take us a little bit longer to penetrate that market.

Dana Flanders
Analyst, Guggenheim Securities LLC

Q

Thank you.

Operator: Thank you. The next question comes from the line of Chris Schott from JPMorgan. Please ask your question.

Christopher Schott
Analyst, JPMorgan Securities LLC

Q

Great. Thanks very much for the questions. Just to follow up on a few topics from before, maybe the first on AJOVY. You're obviously highlighting the autoinjector as driving reacceleration for the franchise. Just help us understand a little bit how quickly post the autoinjector launch do you expect we'll see that uptake? So as your monitoring kind of how important that's going to be for the franchise, is that something that happens almost immediately? Or do we need to give this a quarter or two to evaluate?

And my second question was on TRUXIMA and that opportunity. Is this largely a new start opportunity? Or do you think there is the potential to convert existing patients as well?

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And just finally, a really quick one on taxes. You stepped up the tax rate to 18%. Is that a decent run rate to think about for Teva on a go-forward basis? Thanks very much.

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

Thank you for the questions. I think, Brendan, you will take the first two, and then, Mike, you will take the last one.

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

Sure. So as far as the autoinjector with AJOVY, I don't expect that we'll launch the autoinjector, and all of a sudden, we'll pop up to 30%, 40%, 50% in new to brand share. I do think that we will see a steepening of the curve. And I think that we'll continue to see growth in AJOVY kind of back to the 20%, 25%, 30% that we're looking for as far as new to brand share.

How long that takes? I don't know. I don't expect it to be immediate. But I expect us to continue to grow and climb into that 20% to 30% new to brand share that we're looking for.

As far as TRUXIMA goes, I would expect that you won't see many conversions of patients currently on therapy. I think this is as good – I think that whether it's TRUXIMA or whether it is any biosimilar in an oncology setting, it's probably going to be mostly driven by new patient starts.

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

Yes. And when it comes to the tax rate, I did say in the past that we would see some pressure on the tax rate. And we would eventually get towards the 18%.

We have gotten there a little quicker than we thought. We thought we'd be more in the 16% range this year. But I think 18% is not a bad range for the next couple of years.

In the outer years, of course, maybe we'll be able to bring it back down a little bit. But given our business and given the rules that we're dealing with, with no significant new changes in tax legislation, 18% is a reasonable run rate for the next couple years.

Christopher Schott
Analyst, JPMorgan Securities LLC
Q

Thank you.

Operator: Thank you. The next question comes from the line of Akash Tewari from Wolfe Research. Please ask your question.

Akash Tewari
Analyst, Wolfe Research LLC
Q

Hey. Thanks so much. So if we look at your long term guidance projections for your operating margin, can you – and let's just say we put in consensus top line revenue projections, there seems to be an embedded OpEx cut that's baked in over the next few years, maybe to the order of $500 million to $1 billion. Can you give us a sense

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of how much cost can still be cut out of Teva's current cost structure? And given kind of the pricing wars we're seeing on CGRPs, is that kind of possible?

And maybe on the other line for Teva's US business, can you give us a sense of what the growth trajectory of that line is over the next few years? And what the margins are for those products? Thanks.

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

So I'll try and handle the first part. And then I don't think we have much comment on the margin for us, but we will see what Mike will comment on that.

So if you look at our long term financial targets, then we have an operating margin target of 27%, which is, of course, higher than where we are right now. Now you have to imagine that that improvement will basically come from, you would say, three main sources. One is the gross margin improvement that again will come from the source of optimizing the manufacturing network, which basically takes down the cost of manufacturing per product and thereby improves the gross margin.

And then, of course, there's also a mix effect on the gross margin. When COPAXONE goes down and the generic business is stable, then, of course, your gross margin goes down. When COPAXONE has sort of flattened out, and AUSTEDO and AJOVY are increasing, and your generic is roughly flat, then your gross margin goes up. So those two elements, of course, they help us.

And then, of course, you have the ongoing optimization of the rest of your operational cost. And you're right. We've just taken out $3 billion of the spend base. And we can't do that once more. But of course, we can keep on looking for optimization and improvement. And we'll be doing so going forward.

On the other line in the US, do we comment on that? I don't think so, Mike, but over to you.

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

No. I think you can see the basic sales trends there. This is all the remaining products, many of which are already facing generic competition, so you will see them slowly decline. They tend to have good operating margins, because we don't invest behind these products. So that is something.

But you can see over the course of the last couple years that number has gotten down to a reasonable amount. And it's been pretty stable throughout the year. So you'll see a slow drag. But it's not going to fall off the face of the earth.

Akash Tewari
Analyst, Wolfe Research LLC
Q

Great. Thanks so much.

Operator: Thank you. The next question comes from the line of Jason Gerberry of Bank of America. Please ask your question.

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

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Great. Thanks for taking my question. Just first, Kåre, just curious if you can comment at all on a [The] Wall Street Journal report that came out a few months ago about the possibility that opioid manufacturers are contemplating opting into Purdue's bankruptcy proceeding, while not filing for bankruptcy themselves, but leveraging that legal proceeding.

Which would seem to us to potentially offer you expedience and a consolidated legal mechanism to work with your counterparties. So just curious, what are the impediments to that?

And then just secondly, on November 22, I think there's a deadline for a party's municipalities to opt into a negotiating class. Curious if you view that as a major milestone in terms of your ability to strike a settlement that is global and all-encompassing with the political subdivisions? Thanks.

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

Thanks for that question. So you're absolutely right that there is a theoretical opportunity of seeing the Purdue bankruptcy sort of being expanded to cover the whole, you could say, situation on opioid litigation.

However, as of today, that's not what we're pursuing. As of today, we strongly hope and believe that the framework we have developed together with other defendants and together with the state AGs, that that is the most likely and the best way forward. As I've said before in this call, for the American population and also for the people who suffer from addiction, this will be, in my mind, the most constructive way to move forward.

In the event that this would not work out, of course, you're right. There is another legal framework, which would be some kind of participation from the – you could say, from a legal point of view of all these defendants in some overall resolution under the bankruptcy proceedings of Purdue.

But that's really not what I see as the best solution right now. I think there's more momentum behind the general framework that we have developed together with the state AGs.

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

Next question?

Operator: Thank you. The next question comes from line of David Amsellem of Piper Jaffray. Please ask your question.

David Amsellem
Analyst, Piper Jaffray & Co.
Q

Thanks. So on AJOVY, just irrespective of the autoinjector, do you think you need to contract more aggressively longer term, given how your competitors have contracted, particularly [Eli] Lilly with Emgality being pretty aggressive in year one? So that's number one.

And then number two on AUSTEDO. Your competitor is now going to be running a trial in Huntington's chorea. So with that in mind, how do you see the competitive landscape? Particularly in Huntington's, where you do have a unique label there, how do you see that evolving to the extent that INGREZZA gets a label expansion for Huntington's chorea longer term? Thanks.

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

A

Okay. So I'll take obviously the AJOVY question first. I think that if you look at our focus on AJOVY, it has been on profitability as well as access and share. And I think that we've taken a little bit different approach in regards to access.

But as I said earlier, we have 70% acceptable access. And we continue to – we hope to continue to grow that. So I don't think that we necessarily need a more aggressive contracting approach with AJOVY to be successful.

I think again, the autoinjector is not going to be everything. But we do have kind of a revised commercial strategy and plan around AJOVY, which includes targeting physicians and a whole host of things. So I think that the [ph] gross to net (57:55) is fine. And I think that we don't expect a new aggressive contracting play for access.

As far as AUSTEDO goes, I think that if you – we'll see where INGREZZA goes, and we'll cross that bridge when we get to it. But you're right. Right now, we're the only ones with the HD indication. Whether INGREZZA gets that indication or not, we'll see.

If they do, AUSTEDO certainly has a foothold in that market. Physicians seem to be fairly pleased with the way that AUSTEDO is working. So while it will increase competition and likely take some share, I have no idea how they'll perform in that market.

Operator: Thank you. Next question comes from the line of Umer Raffat from Evercore ISI. Please go ahead. Your line is now open.

Umer Raffat
Analyst, Evercore ISI

Q

Hi. Thanks so much for taking my question. Kåre, I wanted ask a two-part question on opioid settlement framework. And I see two possible layers of alignment that still need to happen. And would really appreciate it if you could give us color on each of them.

So the first one would be the rest of 46 state AGs. And there's a lot of feedback that they're not fully aligned. They're not comfortable. And I was curious if you could catch us up on what exactly is the hold up there.

Second is the cities and counties. And I'm particularly interested in them, because it seems to me that state AGs do appear to be focused on addressing the opioid crisis, so they're okay with taking Suboxone supply. Whereas cities and counties are being represented by trial lawyers, who are primarily focused on their cut on the dollar settlement side.

So in theory, those trial lawyers have no incentive to get the cities and counties to align unless there's dollars coming their way. Wouldn't that theoretically imply a deadlock? I'm just trying to understand, is there a credible path towards resolution in the next six months or so?

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

A

Yeah, so that's of course a very interesting question, which I can't completely answer in all detail, since I'm not a party to all those discussions.

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But if we start from the overall situation. And as I said before, I believe that the framework that's on the table now, that's the best possible way forward to serve the purpose of helping the people suffering from addiction in United States. I think the state AGs see that. I think the other defendants and us, we see that.

And there might be some subdivisions who don't see it exactly that way. But hopefully at the end of the day, what will prevail will be what's best for the American public and for the people suffering from addiction.

And you could also say that if it's not resolved this way, just like the state AGs outlined it, it's becomes a complete random game for which county, which city goes first in the sort of sequence of suing. And how much money do they actually get until potentially some people stop settling or stop paying.

So I think we need a holistic solution here. I think it's to the benefit of everybody to do it that way. And I very much hope that that will be the case.

Umer Raffat
Analyst, Evercore ISI

Q

Great. Thank you.

Operator: Next question comes from line of Gary Nachman from BMO Capital Markets. Please go ahead.

Gary Nachman
Analyst, BMO Capital Markets (United States)

Q

Thanks. Kåre, I know you'll give guidance in February. But with most of the year behind you, how are you thinking about 2019 as a potential trough year and an ability to return to growth next year, both in terms of revenue and EBITDA? Just give some of the major pushes and pulls on that front.

[indiscernible] (1:01:26)

Gary Nachman
Analyst, BMO Capital Markets (United States)

Q

And then just, yeah, just one follow-up. Part of that is that COPAXONE is holding up better than expected. So explain the dynamics there behind the scenes. And can that be maintained into next year? What sort of declines should be thinking about with that franchise? Thanks.

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

A

Thanks. Very interesting question. You're absolutely right, as I've said I guess since I joined, that we were going to do the restructuring. And the decline of COPAXONE combined with the restructuring would actually, from a natural point of view, automatically result in more or less this year being the trough year.

And as you know, a trough is flat at the bottom. And that's what we're seeing right now in terms of the development in revenue and the development in operating profit. You basically see the last quarters being very stable. And we're having the operating profit at the level of just above $1 billion. And the revenues of the level of above $4 billion.

Now if we then think about next year, it's too early for us to give guidance. And then you might ask, why can't you give guidance?

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And one of the elements is, of course, your second question, COPAXONE, because you're right, we are seeing a stabilization. Basically the last three quarters of COPAXONE have been very stable. We see a marginal decline in the TRx volume. We see a very stable development in Europe.

And there's a lot of moving parts in this. And if we take the US first, then you can say, there's the unknown factor of, are we going to have one more generic competitor in the 40mg COPAXONE? Right now, we don't have any evidence that we will have short term, but we don't know when that will happen. So that's one swing factor.

Now that situation will also affect the contracting and the pricing. If there is no new competitor coming in, then there's a high likelihood that the pricing environment will stay relatively stable. Now that will have a positive effect on the outlook for COPAXONE from next year. If all of a sudden there's an approval of a third competitor, then of course, that has a negative effect on the pricing environment.

In terms of share development, it looks pretty steady. I don't expect any major upsets there.

In terms of Europe, we have a situation where we have a patent that's been confirmed in the European patent system, which basically means that the 40mg is covered by European patent as we speak. And that's of course a positive. On the other hand, you have a lot of dynamics on the actual country level in Europe.

But all in all, I would say that there are some swing factors there. But right now they look positive.

And then you have other elements where you can speculate on the [ph] gross to net (1:04:14) will have on AJOVY. How will that whole thing develop? The exact progression path of AUSTEDO, it will for sure grow. But exactly how much will it grow? And you have currencies, how will they develop?

But everything else being equal, unless we don't have a major negative happening, then I still firmly believe that we have the trough year. And we'll see a marginal improvement next year in our operating profit.

We also have things that could happen, such as we have the orphan drug designation that Eagle [Pharmaceuticals] got on BENDEKA, which is protecting both BENDEKA and TREANDA from generic competition. And that has been appealed. And this, it has – actually, the core proceedings have happened. And we are waiting for the outcome of that indication. We hope it will go Eagle's way, so that there will be no change to the situation that BENDEKA has orphan drug designation. But that could also be a swing factor.

So a lot of backs and forth. But I would say everything else being equal, I totally confirm that we expect this to be the trough year. And that we'll see a marginal improvement in the operating profit next year.

Gary Nachman
Analyst, BMO Capital Markets (United States)

Q

Okay. Thank you.

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

So this completes our quarterly earnings call for the third quarter. I very much look forward to hopefully talking to most of you three months from now, when we will announce the full year results and also share with you our look on our future manufacturing strategy and biopharmaceutical R&D strategy. Thank you so much for listening in.

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Operator: Thank you. That does conclude the conference call today. If you wish to listen to the replay of this conference, please dial +44-333-300-9785 and type in the on-call replay code 5965257#. Thank you for participating. You may all disconnect.

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