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Teva Pharmaceutical Industries Ltd.

(TEVA)

Q3 2020 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by, and welcome to the Teva Pharmaceutical's Third Quarter 2020 Earnings Call. At this time, all participants are in a listen-only mode. After the speakers' presentation, there will be a question-and-answer session. [Operator Instructions] I must advise you that this conference is being recorded today.

And I would now like to hand the conference over to your first speaker, Kevin Mannix, Senior Vice President, Investor Relations. Please go ahead, sir.

Kevin C. Mannix
Senior Vice President & Head-Global Investors Relations, Teva Pharmaceutical Industries Ltd.

Thank you, Valerie, and thank you, everyone, for joining us today to discuss Teva's Third Quarter 2020 Financial Results. On the call with me are Kåre Schultz, Teva's Chief Executive Officer; Eli Kalif, Chief Financial Officer; and Brendan O'Grady, Teva's Head of North America Commercial.

We hope you've had an opportunity to review our earnings press release, which was issued earlier this morning. 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.com as well as through our Teva Investor Relations app.

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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 and 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 and Eli will provide an overview of the third quarter performance, recent events, financial outlook and priorities going forward. This will be followed by a question-and-answer session.

Today's call, which will run for one hour, is being webcast live and recorded. You'll be able to replay the call as well as view the transcript later today on the Teva Investor Relations website.

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

Kåre Schultz

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

Thanks, Kevin. Welcome to all of you and thanks for joining this call and thanks for your interest in Teva.

We had a solid third quarter. We saw revenues of $4 billion. That's slightly below our expectation. The reason was that we saw overall lower total script volume in both US and Europe as a consequent of COVID-19 and slightly less patients actually going to doctors and to hospitals for therapy.

When we look at the EBITDA, then the non-GAAP EBITDA came in at $1.2 billion, which is completely in line with our expectations. So, we compensated for the slightly lower revenues by cost savings. We had a GAAP loss per share of $3.97 and that includes a $4.6 billion goodwill impairment. And we had a non-GAAP EPS of $0.58, which was completely in line with our expectations.

The free cash flow was also in line with expectations at $0.5 billion. We are very happy to see a continued reduction in our debt and the net debt as of the end of the third quarter now stands at $23.8 billion.

In terms of business news, we had several interesting things happening in the third quarter. The first one I mentioned here actually happened at the very end of the quarter, the last day of the quarter, that was the very successful launch of the generic versions of the HIV medications, Truvada and Atripla in the US. The sales are all booked in the fourth quarter, but we actually did have the sort of physical launch on the very last day of the third quarter.

We're also very happy that we continued to see the strong penetration of TRUXIMA and we're also very happy about the development of AJOVY and the fact that we are now looking forward to getting it approved in the Japan since it has been sending to the authorities by our partner, Otsuka, in July.

In a very interesting move, we now complement our portfolio of inhalers, digital inhalers, in the US asthma space and we now have launched also the AirDuo Digihaler and the ArmonAir Digihaler, which basically means that we offer a full therapeutic opportunity for people to treat their asthma with our Digihalers, which is a new and very advanced way of treating asthma where you get direct feedback from the device and where your device

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communicates with your smartphone direct to your caregiver. So, we are having high expectations for this going forward.

Last but not least, I'd like to just touch very briefly on the fact that despite COVID-19, which is affecting the whole world and, of course, affects all the countries in which we have our operations, we were able, through resilience of our organization, to remain full operational capacity everywhere and serve the roughly 200 million patients we serve on a daily basis with our essential medicines.

Next slide, please. Today, I actually celebrate that I have been three years with the company as CEO and one of the key things which I'm proud of is this debt reduction you're seeing here. In the three years that have passed since I joined, we reduced the debt to $34 billion, down to $23.8 billion. So, more than $10 billion reduction.

And as you know, it's our ambition to keep on doing this in the coming years. So, I'm sure that in the next three years, we will also see a significant reduction in the overall debt. And that's, of course, important, because the debt following the Actavis acquisition had reached a level, which was not healthy for the financials of the company long term. So, it's a really good and nice improvement here that we're now down below 5 times net debt-to-EBITDA.

Let's move to the next slide, please. Now, in terms of revenue development, you could say, the last three years, we've seen a significant reduction in revenue as a consequence of the patent expiry of COPAXONE in US and Europe. And now, we've actually reached a level where we have sort of flattened. We have plateaued, stabilized the revenue and we're now looking forward to marginal increases in revenues going forward.

There's a couple of quarters here where we have [ph] ones-offs (00:06:29) and we always have that once in a while. That's the nature of our business. One was when we knew about, that was the fourth quarter in 2019 where we made a launch of cinacalcet that boosted, as you can see, the North American sales that generic launch and then there was the first quarter of 2020, where in Europe, we saw a patient-level hoarding of all kind of products, generics – all kinds of products which happened just at the arrival of COVID-19 before the lockdowns and that's why you see the European sales jump in the first quarter this year.

Then, there was a reverse of that jump in the second quarter. So, you see the European sales go down from $1.4 billion in the first quarter to $1 billion in the second quarter. And now, you're seeing more of a normalization. And I would say the European and US sales in the third quarter, they're probably around 5% below the normal run rate than our market share would carry. We've not lost any market share. So, it's really that the volume in the market is still somewhat negatively affected by COVID-19.

We do hope, of course, that, in the coming quarters, we will see a normalization, so that we get back to the normal total market size. And then, of course, in the fourth quarter, we will see the benefit of this, so far very successful launch of Truvada and Atripla in North America. So, a little bump up there in North America in Q4.

And move to the next slide, please. So, as you know, we have three main drivers that will drive our revenue up and then we have one very stable element. And the three drivers that will drive our revenue up, they are two key products. The first one is the one we are looking at now, AUSTEDO.

AUSTEDO has had a really good track record since its launch at the end of 2017, which is actually exactly three years ago. And you can see still it keeps growing strongly. Also here, there are some ups and downs per quarter. That's just random moves in the pipeline, so to speak, or in the value chain. The main thing here is it keeps increasing. It's 64% up versus the same quarter a year ago.

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And we're now above 10,000 patients. And I know I mentioned this before, but it really is important to realize that the 10,000 patients is a combination of Huntington's disease and tardive dyskinesia. And the potential for tardive dyskinesia in the US is huge. There are roughly 500,000 patients suffering from tardive dyskinesia in US and, of course, not everybody will all get therapy. But I'm sure that in the following years, we'll see more patients in therapy than we have right now. So, I'm very optimistic that we'll see a continued strong growth of AUSTEDO in the coming quarters.

If we move to the next slide, please. Now, the second element that needs to drive our growth worldwide is AJOVY. And here, we have actually quite an interesting development. First of all, let's start with a negative piece. The negative piece is that the sales were $35 million and we would like to see them higher. And that's partly because our TRx share is a little bit low now due to the fact that we lost NBRxs, we lost traction in the market in the beginning of this year basically due to the fact that we did not have an auto-injector and the two competing products both had an auto-injector.

Now, we have launched the auto-injector back in May and what you see here is something that I've only seen, I think, once before in my 30 years in pharmaceuticals. It's a really successful re-launch, in this case driven by a device. And what you see is that the capture rate sort of has more than doubled in a few months from being close to 11% to now being nearly 25%. And you can see now that it starts to carry through to the TRx count. So, I'm very optimistic that we will continue to see AJOVY growing nicely.

And I can tell you it's not on this slide, but in Europe, we see the same very nice development in a big market such as Germany where we also launched the auto-injector. We also see a constantly growing market share also to the same level of sort of 20-some percent. And I expect that this market share will continue to grow throughout next year, both in US and in Europe.

So, not the high revenue number we would have liked to seeing, but some really, really good indicators here that AJOVY will show strong growth next year both in US and Europe.

Next slide, please. Another element in our strategy, and here I refer to our R&D strategy that we disclosed some time ago, is biosimilars. And those of you who have followed the company know that I've been saying, before we launched TRUXIMA a year ago, that we wanted to prove that the US market is really open for biosimilars. And if you had the right commercial setup, you can actually penetrate nicely. And there's a new situation in US where it's possible to make a good business and get nice market shares with biosimilars.

And I think I promised from the beginning that the success criteria would be that we needed to get a double-digit market share within a year. And what we see here is that we have a double-digit market share, which is good. It's just around 20% right now. I believe it will keep on increasing in the coming quarters. And we're very, very satisfied with the launch of TRUXIMA.

And this is, of course, important because it's a good launch, but it's also important because, as you know, we have more than 10 biosimilar products in our pipeline now for North America for the US market and this is just validating the commercial model that this is a business, which is a really good supplement to traditional old generics. And we're looking forward to launching many more biosimilars going forward.

One of the reasons why we think that TRUXIMA will keep on growing is really that it's the only biosimilar, a rituximab biosimilar, that has RA indication as part of its label.

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Next slide, please. So, we are looking into hopefully a marginally growing revenue in the coming periods as a consequence of these growth drivers I just described. And of course, combined with the fact that COPAXONE keeps declining, but keeps declining less than these three elements are growing. But that's not the only thing which goes into our sort of optimization of the business. We are also working very hard on improving the operating margin both through the gross margin and through total improvement in our business model.

And here, you see how we bottomed out at 24.5% in 2019, how the guidance that Eli will go through a little later where we narrow the band on the upper end of the earnings guidance. Here, you can see how the band for the operating margin is now somewhere between 25.5% and 26%. And you also see our long-term financial targets of 28% in 2023. And this is the target that we set more than two years ago just after I joined Teva and this is the target we are firmly committed to and all our optimization of the business is driving towards achieving this target, which is very, very doable.

Now, [ph] just taking (14:15) to the next slide and here, I have the same slide as you see many times and this is basically a slide that's been unchanged for a couple of years. And I think it will stay unchanged hopefully for next three years until we get to the point where we actually realize the numbers which will be at the end of 2023, which is three years from now. First of all, we are committed to the 28% operating income margin. We are committing to cash earnings above 80% and we are committed to getting the net debt-to-EBITDA below 3 times. And of course, the way to do so is to utilizing our cash flows to pay down debt and we do not plan to raise any equity.

And on this slide, I would like to actually reflect a little bit on the last three years with Teva, because it has been a phenomenal journey operationally together with my management team and all the employees. I think everybody has done a fantastic job in optimizing the company, restructuring the company, securing a healthy margin, despite a revenue loss of around $5 billion on a yearly basis, getting good control on the cash flow and keeping on paying down the net debt.

I would like to share with all our shareholders who are listening that it is, of course, frustrating that when you're operational plan actually was executed completely according to plan and you see your whole organization doing a great job that you then have legal situations – litigation situations in the US, which are related to events way before you joined the company, litigation situations that gets worse than what you saw before I joined the company three years ago.

Now, that is something, I think, I share with everybody that both the opioids and the price fixing has developed to be, especially the opioids, more complex than was foreseen maybe three, four years ago. And it is a fact that if we look at the share price in the markets, the value of the company, then it is actually, I would say, decreased or held down by the overhang from the litigations and, of course, we would love to solve these litigations.

We are still in a constructive positive dialogue with the state AGs on the opioids. And as you know, we are going to trial with DOJ on the price fixing. So, we believe that, in both these cases, we will eventually see a good settlement of the situations. But it is, of course, a frustration that right now we do see the market cap being held down by these legal situations.

Now, on that note, I will hand over to Eli Kalif.

Eli Kalif

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

Thank you, Kåre, and good morning and afternoon to everyone. As always, we start with the review of the GAAP performance on slide 13. Revenue in the third quarter of 2020 were approximately $4 billion, a decrease of 3% in

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both US dollar and local currency terms compared to the third quarter of 2019, mainly due to a lower revenue from generics, OTC and COPAXONE in all regions and low revenue from QVAR and BENDEKA/TREANDA in our North America segment as well as a reduced demand for certain products resulting from the impacts of COVID-19 pandemic, partially offset by higher revenue from AUSTEDO and AJOVY.

Teva posted a quarterly GAAP loss of $4.35 billion, a loss per share on a GAAP basis of $3.97 for the third quarter of 2020. The significant year-over-year decline was mainly due to a $4.6 billion goodwill impairment which I will discuss on the next slide.

On slide 14, we can see the impairment, restructuring and other non-GAAP adjustments, which totaled approximately $5 billion for the quarter. The majority of this amount was the result of a $4.6 billion goodwill impairment that was booked to the North America reporting unit in connection with current market capitalization influenced by uncertainty regarding the timeframe or resolution of certain litigation.

The company is committed to its projected threshold target and management view on the litigation exposure have not changed. However, recent developments indicate the timeframe for resolution will take significantly longer than previously expected. As such, for accounting purposes, management has incorporated these factors into its valuation of the North America reporting unit, resulting in an impairment charge of $4.6 billion. Amortization was $251 million for the third quarter, aligned with the range of $250 million to $260 million per quarter that we guided to the beginning of the year.

Now, turning to our non-GAAP performance on slide 15, again, we see modest year-over-year decline in quarterly revenue, which I addressed in my opening remarks.

Looking down the P&L, gross margin was 52.4% in Q3 2020 compared to 51.4% for the same period in 2019. The higher gross margin was mainly due to improvement in our operating network coupled with increased sales of AUSTEDO with a high gross margin, partially offset by decline in the generic business as well as our legacy specialty brands in the US.

Year-to-date, our gross margin is 52.5% versus 51.5% in the full year 2019. As Kåre mentioned, we remain on track to reach our long-term financial target. The year-to-date improvement in the gross margin is a reflection of our ongoing development plan to operate with the most optimal manufacturing and efficient overhead cost structure. Looking ahead at Q4 2020 and for the full year, we expect our gross margin to reach the level of 52.5%.

Operating income in the quarter declined by 3% compared to the same period of 2019. While our operating margin of 25.8% for the same quarter was in line with Q3 2019. Still, our year-to-date operating margin was 26.6% versus 24.5% in the full year 2019.

In the first nine months of 2020, operating expenses were $201 million less than the same period last year. As part of our long-term financial target, the company continues to manage expenses and fundamentally reposition the overall operating expenses structure with a view that disciplined cost structure can provide incremental earning leverage as revenues stabilize and begin to grow again.

Looking at Q4 and the full year, we expect our operating margin to be stable at the level of 25.5% to 26% as Kåre notified earlier. Non-GAAP earnings per share in the third quarter were $0.58, in line with the same period last year and bringing our year-to-date non-GAAP earning per share to $1.89 versus $1.78 last year.

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Turning to slide 16, I would like to touch briefly on our spending. Despite the quarterly fluctuation in the top line this year due to the COVID-19 pandemic, we have done a good job managing our overall spend base. Our spend base in this first nine months of the year was just under $9 billion, a decrease of $381 million versus the same period in 2019.

The reduction in the spend base is a reflection of both the active management of our operating expenses and the ongoing efforts to improve our gross margin through the transformation of our network, which we outlined at the start of the year.

Overall, if we add together the expansion of the both, gross and operating margin, in 2020 compared to 2019, we can see the progress in the main five key levers we introduced earlier this year, procurement cost excellence; network optimization and restructuring; operational and quality excellence; end-to-end supply chain integration; and agile operating model and organization.

Turning to slide 17, we see our free cash flow for the quarter came in at $506 million compared to $551 million in Q3 2019. The sequential decline from Q2 2020 was mainly the result of an increase in inventory. This bring our total free cash flow generation for the first nine months of 2020 to more than $1.6 billion, benefiting from stronger-than-unusual start of the year. Based on the first three quarters and our outlook for the reminder of the year, we're maintaining our guidance for 2020, which is $1.8 billion to $2.2 billion.

Now, turning to our debt development on slide 18, as you all know, our current and long-term focus continues to be on debt reduction. In July, the company repaid $1.2 billion in maturities bringing the total debt repaid this year to $1.9 billion. Unfortunately, due to translation differences, we only saw a modest accretional decline in our net debt total and a slight uptick in our net debt-to-EBITDA ratio, which was 4.92 turn. We continue to expect this ratio to remain under 5 turns going forward and decline each year, reaching under 3 turns by yearend 2023.

As we have noted throughout the year, we have the liquidity and cash flow to cover bond repayments for the year 2021 and 2022 before looking to refinance the 2023 maturities.

So, turning to the financial outlook for 2020 on slide 19, this year has proven to be a most unique year indeed with the global pandemic presenting our operation in all three regions of the world with the challenges that have made it difficult to accurately focus the top line. We need to remember that we are still operating in a very dynamic and highly volatile environment. We are working every day to ensure the health and wellbeing of our employees worldwide while managing through a perfectly changing local condition at our locations worldwide.

Our financial outlook is, therefore, based on our current visibility and information that is available today and does not reflect any unexpected impact of COVID-19 on our businesses. Throughout the year, we have seen a significant effect that has on the purchasing pattern of our large global customers and overall utilization by patient.

In Q1, we experienced stronger-than-expected revenue of pandemic-related products and customer stocking. This effect was offset in Q2 and we saw a continued decline in Q3. As a result of this and based on performance of the first nine months, today, we're adjusting our guidance range for full-year revenue from the original range of $16.6 billion to $17 billion to the new range of $16.5 billion to $16.8 billion. This lowers the midpoint of our range by $150 million.

The new range includes adjustment to our full-year expectation for global sales of COPAXONE and AJOVY. For COPAXONE, we are raising our guidance by $100 million to approximately $1.3 billion. For AJOVY, we are lowering our guidance by $50 million to $200 million for the reasons Kåre mentioned – described.

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For our other financial target for 2020, operating income, EBITDA and earning per share were tightening the range by bringing up the lower-end for each one reflecting the reduction in the spend base that I just outlined a few minutes ago. Free cash flow guidance, as I already mentioned, remain unchanged. Where we end up within each of these range will be determined mainly by the rate of recovery in purchasing pattern and overall utilization by patients, which has been impacted by the ongoing pandemic as well as our product mix in our generic business for the rest of the year.

And this concludes my review of the third quarter results and 2020 financial guidance. We will now open the call for questions and answers.

Operator, would you please open the call for questions?

QUESTION AND ANSWER SECTION

Operator: Thank you very much. Ladies and gentlemen, we will now begin the question-and-answer session. [Operator Instructions] And your first question comes from the line of Gregg Gilbert of Truist Securities. Please go ahead.

Gregg Gilbert
Analyst, Truist Securities, Inc.

Q

Thank you. Good morning, Kåre. As you pointed out in your prepared remarks, the company is executing well against the targets that you and the team have laid out, that your equity continues to be held back by liabilities that you inherited. So, I was hoping you could comment or update us on those liabilities.

On opioids, it looks like J&J and the distributors have very recently updated their financials to reflect what could be a near-term settlement. So, on that, perhaps you could weigh in on whether Teva is linked into that or not or on your own?

And then, on price fixing, you previously expressed, in our view, open mindedness in settling with the DOJ even with a reasonable DPA and the penalty. Has that ship sailed, given your comments about going to trial? Any other color you could offer would be great. Thank you.

Kevin C. Mannix
Senior Vice President & Head-Global Investors Relations, Teva Pharmaceutical Industries Ltd.

A

Kåre, just check your mute button, please.

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

A

So, thanks for that. Very good question. So, on the opioids, we are still in a very positive dialogue with the AGs and that's the same group of AGs, of course, that we did the framework settlement with. And it is hopefully so that we'll see a firm settlement within the foreseeable future.

Now, the problem I've said before and I've also alluded to the fact that one of the triggering points for getting the actual settlement done where everybody signs because there's a lot of parties involved in this, a lot of states, a lot of plaintiff lawyers and so on.

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So, one of the triggering points for getting settlements like this this done is when there is the pressure from an actual trial that all the parties are going to. And I was very optimistic, I guess, about a year ago that the New York trial that was scheduled originally for January, then March, then January, then got even postponed, hasn't happened yet. And then, there was a West Virginia trial that got postponed. So, all of the trials that could trigger that people sign on the dotted line have been postponed.

It's quite obvious that there has been ongoing negotiations between us and the AGs and between the four other companies that are participating in the framework. And I will say that they are maybe more progressed in terms of the fact that they have reached another financial number than they started out with, all of them it seems like. But it's important to mention that, from the beginning, we were five individual companies that were negotiating at the same time with the AGs, but we didn't negotiate a, you would say, combined deal. It's five deals, so to speak. Each company having a deal with the AGs and the plaintiff lawyers.

So, I'm still very optimistic that we will have a chance of seeing that whole thing come to a solution where we see a settlement, where we will be supplying Suboxone to all of the US. And that is really the best solution, because in doing so, we will be able to help people to wean off the issues of opioids. So, that's really what's the situation on opioids.

On price fixing, I'm always open to a settlement if it's a settlement that is reasonable. So, a reasonable DPA with a reasonable fine, that is something, of course, that I can live with. I can't live with having to admit to criminal acts that the company did, in my best assessment, not do. So, that's really why it's moving towards a trial. Sometimes, in these cases, we saw it last with the accusation on speaker programs which we settled not so long ago.

So, sometimes once you get really close to a trial date, you have new people involved and there's new negotiation and it does get settled. Sometimes it actually goes to trial, but it's not that I'm against settling. I'm just saying that we believe that the whole, you could say, a body of evidence is so weak that it makes a lot of sense for us to go to trial.

I hope that clarifies your question.

Gregg Gilbert
Analyst, Truist Securities, Inc.

Q

Thank you, Kåre.

Operator: Thank you. And your next question...

Kevin C. Mannix
Senior Vice President & Head-Global Investors Relations, Teva Pharmaceutical Industries Ltd.

A

Next question?

Operator: Apologies. Your next question comes from the line of Umer Raffat of Evercore. Please go ahead.

Umer Raffat
Analyst, Evercore Group LLC

Q

Hi. Thanks so much for taking my questions. Kåre, I know there's definitely a huge focus on the litigations and settlements. But as we think beyond and we think about the base business, I feel like the one thing investors

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aren't quite hearing is a clear plan on new products, new innovation and the real direction from a base business evolution perspective where real path is laid for top line – sustained top line growth, which people are willing to get excited about and put a real multiple on.

And I would just like to perhaps offer an opportunity for you to lay out your vision. Assuming you do get these settlements over the next 12 to 18 months, where do you see it going? What are the plans to make the next AJOVY and the next AUSTEDO and likes?

And a quick CFO question if I may as well. There is an unusually large gain from American Well Corporation and I wonder if there is other investments of this scale we should be aware of within Teva? Thank you very much.

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

A

Yeah. Thanks for those two questions, Umer. I'll start with the first one about future growth. And it's a little bit of, of course, a long answer I have to give you, because our business is comprised of several pockets or several therapeutic categories. And the underlying business is really the generics and OTC business. And there, we see a quite stable situation in North America and in Europe. And, of course, we have these bleeps in North America when we launched the first-to-file and we make some extra $100 million in a quarter and then, in next quarter, we make some and then not so much.

But if you look at it on the line in terms of volume and in terms of sales, then I would say a very stable business in North America and a business that keeps growing in the coming years low-single digit in Europe, stable pricing environment in Europe and a renewed focus from some customers on the supply chain and on, you could say, the reliability of the supply chain.

And as you know, we have probably the most US, European-centric supply chain of any generics supplier. So, that's really the basis. Not a lot of growth, but stability in North America and some growth in the rest of the world are generics. Then, on the biosimilars, I am optimistic as I just went through that in the coming years, we will see growth in our total biosimilars business. I think it's relatively sustainable due to the fact there will be less competition in the form of there will be several competitors for each product, but there won't be 10 competitors and there's a higher hurdle investment to get in there, which means that prices will most likely be more stable than they are in traditional generics.

So, I also think that biosimilars will contribute to growth. And then, of course, there are the two growth drivers that you just saw. So, you saw here that in the third quarter, if we combine AUSTEDO and AJOVY, we probably did something like $200 million in total and this is growing fast. So, next year, if you do the math, combined, there will be $1 billion and they will keep on growing. So, they will attract a lot of growth and that will go on in, I think, the foreseeable future.

And then, of course, you have the sort of, what should we call it, the possible positive surprise in the shape of fasinumab, because fasinumab has actually finished its Phase 3 efficacy trials. That's one readout on long-term safety that we're getting in the first quarter. We are two companies or – we're actually four companies, but two products in development for this action modality in pain medication.

And the ones ahead of us, Pfizer and Lilly, with their tanezumab they have just gotten a AdCom with FDA. I think it's scheduled for March and that basically means that, by March, we will get a good indication of whether their product has a chance of getting approved. Now, the mechanism of action is similar to our product and you can't compare really from trial to trial. I know that. But if you look at it, it doesn't look like there is any significant

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difference in efficacy or safety if you just look at it from an overall point of view. So, if they get a positive opinion and eventually a regulatory approval by FDA, then there's a high likelihood that fasinumab can get the same.

And we just talk about all the negative elements of the opioid situation in the US. It does, of course, have the positive side to it. There's is a huge unmet medical need for non-addictive pain medications and fasinumab could be one of those. So, if fasinumab makes it, then we will, for the next many years, have not two, but three main specialty products driving our top line. After that, as I said also before, the broad range more than 10 biosimilars we have in the pipeline for the US.

And then the other exciting things we don't talk about so much, but actually we just had the end of our Phase 3 program for a long-acting antipsychotic based on a new modality, new formulation, for creating the long – the prolonged action profile.

And as you know, in schizophrenia, the preferred solution is really long-acting products. And here, we've made sort of a version of risperidone, which is longer action and subcutaneous, which basically means that, from a patient point of view, it should be by far the preferred product. Now, we don't have the readout of that Phase 3 trial yet. We will have that sometime in the first quarter.

And there are two to follow, olanzapine, lurasidone are to follow. So, we do have a lot of different things that can drive growth in the coming years.

So, that was a quite a long answer, but it really basically means that I'm optimistic that we will see not dramatic revenue growth, but single-digit revenue growth over the coming years, everything else being equal. And, of course, in these COVID times, I can't promise you anything. We need to wait until we give the guidance for next year in February, but if you ask me about the longer-term outlook, that's how I see the growth drivers, the key ones.

Then, you asked a question about American Well. It's correct that we have a minor shareholding in American Well and we are flagging that in our quarterly accounts. Right now, we don't have any other holdings that are sort of in a situation where they would sort of, based on my sort of predictions for the coming year, pop up as having a major cash value.

Thanks for the questions.

Operator: And your next question comes from the line of Ronny Gal of Bernstein. Please go ahead.

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

Q

Good morning and thank you for taking my questions. Kåre, I'd like to talk a little bit about biosimilars, because [indiscernible] (39:40) I think this is real interesting growth drivers. I guess of the 10 products – let's just start with the 10 products you have in the pipeline. Could you share with us any name products before 2025?

And out of those 10, how many are yours only versus how many are you sourcing from Celltrion or in other partners? That is kind of like what's your share of the margins here?

And then, specifically around the Humira biosimilars, if I may finish on this one, specifically around the Humira biosimilars, I haven't seen a settlement for you with AbbVie, so I have no good idea about when you're going to

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come in. And it seems you are doing its interchangeability trial. If you can comment on that, tell us when you expect those results and how do you think it positions you in the marketplace?

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

Yeah. So, first of all, out of the, let's say, roughly 10-plus biosimilars we have in development or where we are waiting for approval and launch in the US, it's 50/50 between internal development and things that we have insourced. You saw the Alvotech deal, which we announced just recently. So, we basically have half coming from that deal and half coming from our own internal development.

And then, I have to just point you that for competitive reasons, we have so far decided not to comment on any specifics. It's not difficult to guess some of them, I'm sure, because we are basically going for roughly the 10 biggest, because that makes the most sense. So, I'm sure you can guess most of them, but we've actually decided not to comment on the actual timing and the actual products and that's really for competitive reasons. So, I'm sorry about that.

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

Appreciate it.

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

Thanks for the question.

Operator: Thank you. And your next question comes from the line of Elliot Wilbur of Raymond James. Please go ahead.

Lucas Lee
Analyst, Raymond James & Associates, Inc.
Q

Hi. Good Morning. This is Lucas Lee on for Elliot and thanks for taking my questions. So, the top line outlook is lower by $100 million with COPAXONE outlook increased by $100 million and AJOVY down by $50 million, implying $150 million reduction in other areas. So, what are the primary factors accounting for that?

And if I could sneak in a product-specific question, AJOVY sales have been lighter than expected given absolute and relative growth as measured by Rx trends. Could you help us understand the dynamics there? Is this a function of heightened rebate pressure or were there other one-time factors leading to the flattish sequential top line? Thank you.

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

Thank you. So, your math on the top line is absolutely correct. And the $150 million that we talk about here is basically related to the lower total script volume in the US on a lot of different products, including generics, and the same thing in Europe. What we saw was we saw first a increase in volumes in the first quarter and we saw a significant decrease in volumes in the second quarter to the tune of maybe 15%.

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And then, in the third quarter, we've seen on average, because there is, of course, ups and downs from different lines of business and so on, but on average on both our sort of all the specialty products and our generics, we are seeing something like a 5% reduction in total script volume across Europe, and across United States, so the total TRx in the marketplace. And that's why I'm saying that this reduction of, let's say, $150 million is basically related to that volume reduction and not to any change in our, you could say, market shares in Europe or in US.

And, of course, we hope it's probably – right now, it's difficult to predict as you know. We hope that in Europe, people are getting more used to that doctors are open, the pharmacies are open. I know we have a lot of lockdowns in Europe right now. But none of those lockdowns include doctors, none of those lockdowns include pharmacies. So, we see that there's a, you would say, asymptotic approach to the normal volume and we hope we'll continue to see that in the fourth quarter. And in the US, as you also know, in most states, there is a quite open situation with also pharmacies and doctors and so on, trying to get back to normal. So, that's really the reason for that.

If we look at AJOVY, then I already commented on the fact that the TRx are lower than we had expected. And of course, we are catching up now, with NBRx getting back up to around 25%. The TRx will – of course declining nicely here also in the fourth quarter.

The only other factor which has affected it is really the fact that some of these neutral brand scripts that we're seeing now, they do get a buy-down support in the initial phase. And that means that if you have a high volume increase in NBRx versus a stable TRx volume, then you get slightly less net sales out of that due to your buy-down coupons. We have not seen any changes in the contracting environment. So, we've not seen any increases in the rebates given on the various contracts.

I hope that answers your question.

Lucas Lee
Analyst, Raymond James & Associates, Inc.

Q

It does. Thank you.

Operator: Thank you. Your next question comes from the line of Akash Tewari of Wolfe Research. Please go ahead.

Akash Tewari
Analyst, Wolfe Research LLC

Q

Hey. Thanks so much. So, you guys took a pretty significant goodwill impairment charge regarding uncertainty on resolution of certain litigations for your North American business. Can you talk about what leads that? Does it have anything to do with generic Revlimid? And is there any comment on when that product is getting on to the market?

And then, is it fair to say there wasn't an ongoing civil liability on the generic price fixing side? You would have more strongly considered a settlement with the DOJ. What are the legal ramifications long term of admitting guilt in regards to the civil liabilities? And is there a timeframe for the DOJ resolution and then the civil liabilities resolution on price fixing? Thank you.

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

A

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Okay. Thank you. I'll give the first question to Brendan and then I'll just take the price fixing now.

So, on the price fixing, it's correct, there is, of course, a criminal side to DOJ and a civil side to DOJ. And then, we also have a legal situation with the state AGs on price fixing. And you're absolutely correct. If we, as a company, were to admit to a criminal act on price fixing, which we did not commit, then you would sort of take away your own dissent on the civil side whether it's with DOJ or whether it's with the AGs.

And typically, you will often be able to reach a solution with the DOJ that from a financial point of view is something that you can accept given the circumstances and the hassle of going to trial. But it's more uncertain how it looks with the trial that the civil – the civil AG trial, because that's a more broad-based accusation they are raising. And if you were to go along with that, which is in our view unfounded, then that, of course, would have a potentially higher financial cost. And that's exactly right. That's one of the reasons why we did not want to settle with DOJ with a DPA that would force us to [ph] admit (47:29) criminal conduct which we have not conducted.

And on the first one, I don't know whether Brendan or Eli can answer that.

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

So, Kåre, I'm hearing you loud and clear, but the question was a little muffled. I'd be happy to address it. Could you just repeat it for me or have him repeat it?

Akash Tewari
Analyst, Wolfe Research LLC
Q

Yeah. No problem. So, if you can hear me, if goodwill impairment charge, $4.3 billion, on North America regarding uncertainty on certain legal timing, what is kind of leading to that big step-down on goodwill impairment? And does it have anything to do with generic Revlimid? And when could that project get on to the market, given the Dr. Reddy's settlement? Thank you.

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

Yeah. So, maybe you could talk about the Revlimid, Brendan, but I'll just give a brief answer to the first part of it. So, the reason for the adjustment, the main reason for the adjustment is, you would say, accounting technical, the fact that there is a discrepancy between the net assets that we are showing in our accounts, before this write-down, and then the market capitalization.

And if you have that for more than a year, then it's good practice to take a good look at it and look at whether you should adjust your accounting, in this case, the goodwill, to bring your market cap closer to the actual or rather bring your net assets closer to the market cap. So, it has nothing to do with the Revlimid. It is just an overall assessment that there are factors in the market that probably will continue such as the opioid litigation and price fixing litigation.

We do believe that due to COVID-19, this could be very prolonged. They could go on. The price fixing litigation could go on for years. And as a consequence of that, we can't say that the overhang on the share price will be removed soon. And as a consequence of that, we decided to make a write-down on the goodwill

But maybe, Brendan, you can comment on the Revlimid.

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

A

Yeah. So, Kåre, I'll just make a comment on the Revlimid piece. We typically don't comment on settlements for obvious reasons, the confidentiality and we typically don't comment on the dates of particular launches. So, I'll just leave Revlimid at that and leave it with Kåre's answer.

Kevin C. Mannix
Senior Vice President & Head-Global Investors Relations, Teva Pharmaceutical Industries Ltd.

A

Thank you. Next question?

Operator: Thank you. Your next question comes from the line of David Amsellem of Piper Sandler. Please go ahead.

David Amsellem
Analyst, Piper Sandler & Co.

Q

Thanks. Just a couple. So, wanted to get your thoughts on the longer-term trajectory of AUSTEDO. As we all know, Neurocrine is running a study of valbenazine in Huntington's chorea, which should read out next year. Do you think that's something that, to the extent that they get a label expansion, could prove to stunt the growth of AUSTEDO over the long term? That's number one.

And then number two, you have some high-value generics, FORTEO, NuvaRing. To the extent that those don't bear fruit in a timely manner next year, I mean is that something that you think could have an impact on the trajectory of the generics business, particularly considering you have a more competitive landscape for biosimilars? How should we think about that to the extent that you have sort of a paucity of launches next year if that comes to pass? Thanks.

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

A

Thanks a lot. So, in terms of AUSTEDO, like I said, when I comment on the development, AUSTEDO and the competitive product is actually in a very good position, where they are the first products approved for tardive dyskinesia. There are only two products approved for this disease. I think we have around 10,000 patients. They have around 15,000 patients on drug and the patient pool, just for tardive dyskinesia, is around 500,000 and maybe only half of that will ever get on active therapy. But it just means there is a big potential.

And the competitiveness is you could say quite similar and reflected in the patient counts due to the fact that INGREZZA launched a little bit ahead of us. So, they're a bit ahead, but I think the growth in patients is pretty similar between the two companies. So, I don't see that their potential approval in Huntington's would make a major change in the market dynamics. So, I'm very optimistic that due to the huge unmet medical need, we will continue to see AUSTEDO growing for the next many years.

With regard to the high-value launches, then you can say, of course, it always gives a little positive belief. I just showed you the cinacalcet in 2019 and we're going to have Truvada and Atripla here in the fourth quarter of 2020. And most likely, every year, we get one of these key more complex high-value drugs approved. We still have the EpiPen and so on. So, I don't think it's going to play a major difference to what we see in terms of earnings and revenue next year.

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But maybe I don't know, Brendan, if you want to give a specific comment to some of these high-value launches.

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

Sure, Kåre. I'd be happy to. So, we have numerous potential high-value launches that are always possible next year. There's five or six of them. We'll see as we move through the regulatory process, which ones get approved and which ones don't. And you're right, the market can change by the time you get approval and launch. But the way that we certainly account for those and risk adjust those in our P&L takes all that into consideration. So, I'm optimistic next year we'll have several high-value launches. We'll see how that goes, but that's generally the way it plays out.

And the only other thing that I would add on AUSTEDO is that there is a significant number of patients out there, as Kåre said. About 5% of the market, available market, is treated between us and our competitor. So, we do see significant upside potential with tardive dyskinesia. And tardive dyskinesia represents the majority of the growth and the value. Huntington's disease is important, but tardive dyskinesia is certainly the bigger market. So, I'll just – I'll leave it there.

Operator: Thank you. Your next question comes from the line of Randall Stanicky of RBC Capital. Please go ahead.

Randall Stanicky
Analyst, RBC Capital Markets LLC
Q

Great. Thanks. Kåre, it looks like you're reaffirming your implied EBITDA target in 2023 of close to $6 billion on the assumption that you can take down debt, net debt, by a couple billion a year and get under 3 times on net leverage. So, that seems to imply revenue growth of 2% to 3% on your 28% margin, EBITDA growth mid-to-high single digits. So, first question is, is that the right way to think about the outlook on those metrics?

And then, secondly, can you talk about the digital therapeutics opportunity on the back of AirDuo and ArmonAir? Are there additional opportunities as you think about the broader base of business, either brand, generic or biosimilar? And do you see a 505(b)(2) opportunity in digital therapeutics? Thanks

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

Thanks. So, the first question, you are, of course, all spot on there. We will probably have a cash flow $2 billion, $2 billion-plus per year. And we'll allocate the cash flow to debt reduction. So, that means, in the next years, we'll take some $6 billion-plus out of our debt. And that of course, you said the math is quite straightforward, that EBITDA should be around $6 billion. And the way to get to that EBITDA is also pretty straightforward, because we've already sort of explained to you what we think the operating margin will be, because that's going to be 28% in the end of the period.

And then, of course, you can calculate, as you rightly did, that we need a low-single-digit growth in revenues in order to get to there. And that's what we believe we can do. And the reason why you believe we can do it is what I explained to Umer based on his question with the various elements going in and contributing to a combination of stability and growth. And when you add all that up, you get to single-digit growth rates on the revenue. So, that's really our plan.

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With regards to your second question, then our first comment on the actual Digihalers and then our comment on the further possibilities within the digitization of pharmaceuticals, so on the Digihaler, it's, I think, extremely exciting, because here we have a product that fits perfectly with the unmet patient needs. Because if you are on asthma therapy, then there are at least two things that are crucial. One is you take your medication correctly. And two is that you monitor or somebody else helps you monitor your disease, so you avoid hospitalization and severe asthma attacks.

Now, the Digihaler platform, and sorry for giving a slightly long answer, but it really consists of a normal inhaler, but inside the inhaler, there's in-built a flow meter that registers whether your flow and your inhalation is a good or bad inhalation. That's super important for compliance. There is automated communication through the smartphone, from your smartphone to the cloud, run by Amazon Cloud Services and on from the cloud to any caregiver that you give access. Could be your doctor, could be a nurse, could be your parents, could be your loved ones, anybody who you want to share the data with, you can do it that way.

And by following the patterns, we believe that, both short term by people being more aware of what's going on in their therapy and longer term through artificial intelligence, we will be able to improve the predictability of major asthma attacks and avoid them. And that's a major value driver for the hospital systems and, of course, quality of life for the patients.

So, we are very happy about this. We think we have a great system. We're the first in the world to launch such a system. You have all these other systems where you add something on to an inhaler and whatever. But this is super nice, slick, efficient, built right into the inhaler. We have just launched and we are seeing nice steady uptick and we are seeing a lot of usage already and we look very much forward to sharing because, of course, we collect data on this and that will also give us more medical insights.

Now, that's on the respiratory franchise we have. And as I said, we will keep on building that respiratory franchise now based on the Digihaler both in US and in Europe.

On the more sort of long-term question of does this give inspiration to do other the things, of course it does and I won't sort of share with you today all our ideas, but just say we do have ideas for how we might be able to put this kind of digitalized patient compliance tracking into products that will then also help communication between patients and caregivers and improve the adherence to therapy. And through that, improve the clinical outcomes. So, it's a very exciting year. Thanks for the question.

Operator: Thank you. And your last question comes from the line of Balaji Prasad of Barclays. Please go ahead.

Q

Yeah. Hi. This is [ph] Steven (59:29) on for Balaji. Thanks for the questions. Maybe if you could talk more about the outlook for AJOVY, I guess could you just provide a little bit more color on what exactly has changed from the outlook provided in August? And then, how do you view the additional competition coming into the migraine prevention market over the next one to two years? Thank you.

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

A

Yeah. Thank you very much. So, what really changed has been that the chosen market growth has not been exactly as we hoped for. So, therefore, we are getting a higher TRx number as you saw. We are getting a higher

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indirect share. So, we are getting higher share of the market, which is good. But the chosen market has continued to be held back in its growth compared to what we hope for and plan for most likely due to COVID and the fact that new therapies simply grow slower when people go less to the doctor. And that's the key driver.

The other element that in effect is that we're probably seeing more, you could say, new scripts come in, where we ended up using copay cards and pay-downs and that has led to a slower, you could say, ramp-up of the revenue per script compared to what we were planning for.

Now, next year, we expect to see a continuous growth in the NBRx rate and as a follow-on from that the TRx rate. And as people get on more regular therapy, of course, they don't get the same initial buy-down and that means that the net revenue per script will be going up. So, we are quite optimistic that we'll see a nice development of the AJOVY sales next year, also helped by the increasing number of European launches in the very strong initial performance we're seeing there.

So, thank you very much for that question.

Q

Thank you.

Kevin C. Mannix

Senior Vice President & Head-Global Investors Relations, Teva Pharmaceutical Industries Ltd.

Thank you, everybody. That concludes our call for today. We look forward to speaking to you today, tomorrow and the weeks to come. Thank you, again, for participating.

Operator: Thank you. Ladies and gentlemen, that does conclude your conference call for today. A replay of this event will be available in four hours' time. You can listen to this at any time by dialing +44 3333 009785 and using the conference ID 7275239.

We thank you for participating and you may now disconnect.

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